**IN THE UNITED STATES DISTRICT COURT FOR THE
WESTERN DISTRICT OF PENNSYLVANIA**

BEST MEDICAL INTERNATIONAL, INC. Plaintiff, vs. ACCURAY, INC., a corporation; Defendant.	Case No. 2:10-CV-1043 (TFM)

ACCURAY'S RESPONSIVE CLAIM CONSTRUCTION BRIEF

Kirsten R. Rydstrom
PA ID No. 76549
REED SMITH LLP
225 Fifth Avenue
Suite 1200
Pittsburgh, PA 15222
(412) 288-7284
(412) 288-3063 (fax)
krydstrom@reedsmith.com

Madison C. Jellins
HelixIP LLP
400 Seaport Court
Suite 105
Redwood City, CA 94063
650-474-0240
mcjellins@helixip.com

Janice A. Christensen
HelixIP LLP
New York
Counsel for Defendant,
Accuray Incorporated
650-474-0240
jchristensen@helixip.com

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases

Statutes

I. INTRODUCTION

Claim construction is a pivotal moment in every patent case, often determining non-infringement, and central to any analysis of invalidity. Claim construction can be a difficult and challenging process, but, at its best, it is an art form. Encompassing both technological and linguistic exploration, it requires the Court to "roll up its sleeves," and spend time with the claims, the written description, the file history, the prior art, and expert testimony to come to an understanding of what the claims mean from the perspective of one of skill in the art at the time of filing of the application. Rarely can that meaning be found in dictionary definitions, for there are many dictionaries from which to choose and multiple meanings in each dictionary -- none of which may be the meaning the inventor intended. Moreover, even simple words may have a divergent meaning when used in the context of a claim.

BMI, however, relies primarily on dictionary definitions to advance overbroad constructions untethered to the claims, and uses an outdated claim construction methodology repudiated by the Federal Circuit in *Phillips* and its progeny. Indeed, BMI cites a 2004 article for the ludicrous proposition that the Federal Circuit prefers Webster's 3rd Edition to construe claim terms. The asserted claims, however, cannot possibly be stretched to cover an entire radiation treatment system, like Accuray's CyberKnife, or even the treatment planning component of the CyberKnife system, known as Accuray's MultiPlan Treatment Planning System. The scope of the two asserted claims is much narrower: covering only an improved "optimizer," *i.e.,* a computer loaded with optimization software that runs a specific optimization algorithm known in the art and a "modified" cost function to calculate the intensity of radiation to be administered to a patient on a beam-by-beam basis.

The inventor, a clinician himself, had experienced the frustration of attempting to interpret the output of complicated mathematical algorithms to determine whether a treatment plan was

optimized and resolved to come up with a solution to the problem that clinicians could easily understand. His purported invention was directed to simplifying the output of the cost function incorporated in the optimization algorithm, so that a clinician could simply visually compare graphs (CDVH curves) to determine whether a proposed plan was better than the previous one. The novelty of the '283 patent, if any, lies in the use of partial volume data to create CDVHs, the division of CDVHs into zones, the weighting of those zones, and using those parameters as input for a cost function that is easily interpreted by the user. In an art crowded with a variety of optimization algorithms and cost functions for determining the cost of different proposed solutions of beam weights, Accuray's construction properly "*capture[s] the scope of the actual invention*."

This is one of those cases where it is clear from the manner in which the patentee uses terms within the specification and claims that the patentee intends for the claims and the embodiments to be "strictly coextensive." The specification makes a detailed disclosure of the so-called "modified" cost function, and repeatedly refers to it as "the cost function of the present invention," dispelling any half-baked notion that the disclosure is exemplary rather than limiting. As one of ordinary skill in the art would readily appreciate, if not limited to the particular cost function disclosed at column 13 of the specification, the asserted claims are clearly invalid as anticipated by a variety of references, including the Webb articles, the inventor's own publications on the PEACOCK plan, and a myriad of other references.

Moreover, the inventor recognized the limited scope of the claims when he called his invention an "improvement," emphasizing that his only contribution to the art was the "modified" cost function, repeatedly referred to the "cost function of the present invention," and instead of disclosing details of how the optimization algorithm worked in the specification,

incorporated by reference prior art references disclosing how simulated annealing had been used in inverse planning. He could not do otherwise, as the person credited with the development of the use of simulated annealing in inverse planning for radiotherapy, Dr. Steve Webb, had published widely, had never patented his inventions, and thus had placed his work squarely in the public domain. In fact, the principal inventor acknowledged the importance of Webb's work by purporting to incorporate by reference several of Webb's publications in the specification and relying on them exclusively for the disclosure of the optimization algorithm claimed in the '283 patent. Expert testimony also confirms the proper scope of the asserted claims.

Accordingly, once the two asserted claims are construed and limited to their proper scope, the question of literal infringement will collapse and be suitable for immediate summary judgment of non-infringement in favor of Defendant Accuray.[1] *See, e.g., International Rectifier Corp. v. IXYS Corp., 361 F.3d 1363, 1374-75 (Fed. Cir. 2004); Rhine v. Casio, Inc.* 183 F.3d 1342, 1345 (Fed. Cir. 1999).

II. BACKGROUND OF THE TECHNOLOGY

A. Conformal Radiation Therapy

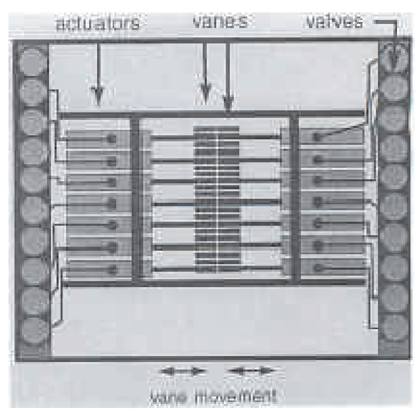
The '283 patent states that the field of invention is conformal radiation therapy of tumors. Radiation therapy is the medical use of high doses of ionizing x-ray radiation, most often to kill malignant cells for cancer treatment. To reach the tumor, therapeutic radiation must pass through normal, healthy tissues. Because ionizing radiation will also kill normal cells, radiation optimizers attempt to minimize the doses to the normal tissues by using multiple shaped beams from many different directions. The dose cumulates, and is highest where the beams intersect at the tumor, known as the isocenter. Conventional three dimensional conformal radiation therapy (3DCRT) shapes the radiation delivered to a target volume as closely as possible to the shape of

[1] BMI has not asserted the doctrine of equivalents for either of the asserted claims.

the tumor target volume while limiting doses to normal structures. The amount of radiation passing through the cross-sectional area of the beam at any moment is called the "intensity" or "fluence". The system is designed to deliver a uniform intensity across the treatment beam. In the mid-1990's, conventional gantry-based systems were commonly used for 3DCRT. In gantry-based systems, the patient lies on a couch, and the treatment source or linear accelerator (linac) rotates around the patient in a single plane. Beams are set at particular orientations and each beam is shaped to the shape of the target. Rosen Dec. at ¶¶ 30-41.[2]

B. Multi-Leaf Collimators and IMRT

Manufacturers began incorporating multileaf collimators (MLCs) into their linear accelerators (linacs) in the 1990's. MLC's were used to shape (or collimate) the radiation beam using narrow leaves of tungsten which had open and closed positions controlled by the computer. A conventional gantry-based system in the 1990's used a binary multi-leaf collimator between the radiation source and the patient to shape the beam as the gantry rotates about the patient. The MIMiC, developed by the principal inventor of the '283 patent, Mark Carol, in the 1990's is an example of such a system. *See* Ex. 2 at 56; Ex. 22 at 58.[3] In binary MLC's, the leaves have only two positions, corresponding to open and closed. The leaves divide the radiation beam into beamlets (or beam elements). The computer controls whether the individual leaves of the MLC are open or closed, and for how long. The amount of time that a leaf is open determines the beam intensity from the particular beamlet corresponding to



[2] Declaration of Dr. Isaac I. Rosen submitted herewith ("Rosen Dec."). Dr. Rosen is serving as Accuray's technical expert for claim construction in this case.
[3] All exhibits are to Accuray's Identification of Extrinsic Evidence filed herewith ("Ex._") or to the Appendix to Joint Disputed Claim Terms Chart ("Dkt. No. 131, Ex. _").

that leaf. While the radiation source is pointing at the patient from a given direction, each leaf can be open for a different period of time, thereby delivering a different intensity from each beamlet. The overall result is to deliver a beam of radiation from that direction whose intensity varies from point to point. Rosen Dec. at ¶¶ 42-52.

The development of MLCs was an enabling technology for intensity-modulated radiation therapy (IMRT). In IMRT, the radiation intensity is modified by changing the shape or collimation of the beam at each gantry angle. As explained above, each IMRT beam is subdivided into many small "beamlets," each of which can have a different beam intensity. Ex. 3 at 19-20. The beam weights of each beamlet in the beam are referred to collectively as an "intensity map." *Id.* at 20. For IMRT planning, there may be hundreds of beam intensities or beam weights for each beam. IMRT delivers multiple beams with non-uniform intensity maps coordinated in such a way that when all of the beams are delivered, the dose distribution inside the patient is optimal. The radiation intensity in each beam is varied across the target such that the dose pattern from all the beams combined produces the optimum dose distribution. Because of the complexities of determining the beam weights for each beamlet of each beam in the treatment, IMRT planning is not possible without computer optimization of the beam weights. Rosen Dec. at ¶¶ 42-52.

C. Treatment Planning

A cumulative dose-volume histogram (CDVH or DVH) is a simple graph that concisely summarizes the volumetric information about the doses delivered to a structure volume. It shows how much volume of the structure receives a dose equal to or greater than a specified dose. The CDVH gives no spatial information about the delivered doses, meaning it does not provide information about the dose delivered to any particular spatial location within the volume represented by the CDVH. Research into using CDVH's in treatment plan optimization goes

back to the 1980's. *Id.* at ¶¶ 56-59, 73.

A CDVH is constructed from the 3D pattern of dose within the patient. Each defined structure (target and normal) within the patient is represented by a set of discrete points (or voxels, defined as a volume element within a 3D image) within the structures. The doses at all voxels within a structure are tabulated to give partial volume data. Partial volume data generally describe what percent of a target or structure volume receives a particular dose of radiation. A CDVH curve for a target volume identifies, for example: (i) minimum dose to be delivered to 100% of the target volume; (ii) maximum dose to be delivered to any portion of the target volume; and a percent of the volume that must receive a certain dose. When these partial volume values are plotted on a graph and connected by lines, they form a CDVH curve. *Id*. at ¶¶ 57-58.

In conventional forward planning, values for all treatment delivery parameters are selected by the planner and the resulting dose distribution is examined. Treatment parameters are repeatedly adjusted manually to improve the plan until all prescription goals, the goals being defined by the CDVHs or partial volume data, are met or until no further improvement seems possible. With the advent of IMRT, the optimization problem for IMRT became much more complex. To deal with these complexities, planners use "inverse planning." Id. at ¶¶ 61, 63-63; Ex. 3 at 20. The user starts with the desired dose distribution and works backward to find the set of beam weights or intensity map for each beam that produces the desired distribution. *Id.*

D. Optimization Algorithms and Cost Functions

Optimization algorithms are mathematical algorithms used in inverse planning and IMRT to find the set of beam weights for each beam that produces the best dose distribution for a particular patient. Rosen Dec. at ¶¶65- 76; Ex. 3 at 20. Research on algorithms for computer optimization dates back to the late 1960's, and there is an extensive body of literature exploring the use of many optimization algorithms. Every optimization problem must have a goal. A

"cost" function is the mathematical description of that goal. *Id.* Every potential solution to the problem has an associated cost, which is calculated by the cost function. *Id*. Typically, algorithms attempt to minimize that cost. Some algorithms are limited in what cost functions they can optimize, and some algorithms are more efficient for a particular cost function than others. *Id*. Every optimization problem also has independent parameters (variables) that are changed to generate potential solutions to the problem. *Id*. A set of values for the variables constitutes a potential solution. In radiation treatment planning, these independent variables are most often beam weights. *Id.*

The cost function and its relationship to the variables define the solution space and the type of optimization algorithm used to solve a particular problem. *Id.* at ¶¶ 65-72. A solution space may have a single minimum, which means that there is one and only one best solution. *Id.* This type of problem can be solved using multiple methods and all will give the same result. *Id.* However, real-world problems are more complex and their solution spaces have multiple minima or potential solutions. *Id*. Each minimum is the best solution within its local region and is therefore termed a "local minimum," but not all local minima are equally good solutions. *Id*. Ideally, the optimization algorithm should be chosen based on the characteristics of the cost function and independent variables. *Id*.

A variety of cost functions had been used in radiation therapy treatment plan optimization before the filing date. *Id*. at ¶¶ 74-75; s*ee* Ex. 1-2, 6-7, 9-17, 20-23. Early cost functions were simple mathematical functions, such as the maximum dose to the tumor that could be easily solved using analytic or deterministic methods. Id. If the relationship can be written as an equation with the value of the cost on one side and the variables on the other side, then the cost function is said to be "analytic". Otherwise, the cost function is "non-analytic." Many

optimization methods, such as linear programming methods, will not work with non-analytic cost functions. Id. at ¶ 70.

In a linear cost function, there is a linear relationship between the cost and the variables. *Id.* at ¶71. In contrast, in a non-linear cost function, the cost does not have a linear relationship with the variables. *Id*. When the cost function is non-linear, it is susceptible to local minima (or multiple solutions) within the solution space and requires a certain type of optimization algorithm to solve the problem. *Id*. Stochastic algorithms, such as simulated annealing, are used to solve these problems because they are designed to escape local minima and find the global minimum (global solution). *Id*. at ¶¶ 72, 84; *see* Ex. 22 at 54-56.

An example of a non-linear cost function is one that uses dose volume variables such as CDVH curves or the partial volume data from CDVH curves. The relationship between the cost and the CDVH is not linear because it is not possible to predict the change in a CDVH (i.e., the area under the curve) from a given change in a beam weight. Rosen Dec. at ¶ 73. As discussed above, the CDVH is constructed from tabulating the doses to all the points within a structure. When beam weights change, the pattern of dose within the structure changes and the doses to individual points change. *Id.* Individual points that previously contributed to one part of the CDVH curve may now contribute to a different part of the curve, and the problem will be susceptible to local minima or multiple solutions. *Id*. More clinically relevant cost functions based on CDVH's require stochastic methods such as simulated annealing. *Id*. at ¶¶ 73-74.

E. Optimization Algorithms: Simulated Annealing

In the mid-1990's, many optimization methods were known in the art for producing an optimized solution, including both analytic and stochastic methods. Dr. Carol was aware of such optimization methods, and the advantages and disadvantages of each:

> A variety of mathematical methods have been explored for producing an optimized solution. Analytic techniques, such as linear and quadratic programming techniques are computationally fast. However, in general, it is not possible to achieve a perfect inverse solution by analytic means unless one allows for negative beam weights…. Thus, even so-called analytic inverse planning methods become approximations, just as is the case with their iterative counterparts.
>
> Iterative or stochastic methods *are exemplified by simulated annealing which* … proceeds by randomly changing beam weights, then evaluating the effect of each changed on the dose distribution. The acceptability of a change is determined by a cost function which is a mathematical quantification of how conflicting goals will be resolved; a higher cost is produced when the resulting dose distribution strays from the desired dose distribution. In general, although not always, the production of a higher cost results in throwing out of the change in beam weight (higher costs are occasionally accepted in order to allow escape from local minima). The iterative changing of beam weights continues until the cost reaches a user-designated acceptable level.

See Ex. 3 at 20-21.

Analytic algorithms, such as linear programming and quadratic programming, solve the problem directly through algebraic operations. Rosen Dec. at ¶ 77; Ex. 3 at 20. Analytic methods are unique in that they do not have multiple proposed solutions, and they do not proceed iteratively from one proposed solution to another. Rosen Dec. at ¶ 77. Rather, through a series of algebraic operations, they arrive at the final optimized solution directly. *Id*.

Other algorithms are non-analytic, and use a search method to solve problems. *Id*. at ¶ 78. In deterministic search algorithms, new solutions are generated based on the shape of the solution space using planned steps whose sizes and directions are intended to produce a better solution at each step. *Id*. at ¶ 81. For a given problem and initial solution, these algorithms will always repeat the same sequence of potential solutions. Further, they always converge to the local minimum nearest to the initial solution, and have no mechanism for escaping from a local region. To use them for finding the best solution in a complex solution space, the user applies them repeatedly to the problem and each time starts with a different initial solution. *Id*. at ¶ 83.

Other non-analytic algorithms are stochastic, such as simulated annealing and genetic

algorithms. *Id*. at ¶ 82. Simulated annealing was appealing for optimization because it is able to find the global minimum in a complex solution space, and it is suitable for use with virtually any cost function, even non-analytic or non-linear ones. *Id.* at ¶84. “The power of simulated annealing lies in the potentially infinite flexibility of choice of cost functions.” Ex. 22 at 60. The advantages of simulated annealing and its variants, including its relative simplicity and the fact that it was well suited for complex many-dimensional cost functions, were well known in the art prior to the filing date of the ’283 patent. Ex.19 at 180.

Simulated annealing generates solutions by using a probability function to randomly select the step size and direction from one potential solution to the next. Rosen Dec. at ¶ 88; Dkt. 131 at Ex. 4. At each step, or iteration, of the simulated annealing algorithm, a new proposed set of beam weights is obtained by randomly adding or subtracting small grains of beam weight. *Id.* The proposed solution of the current iteration is compared to the accepted solution of the previous iteration. *Id.* A proposed solution always becomes the best and is accepted if it has a lower cost. Occasionally, simulated annealing will accept a poorer solution. *Id*. As the algorithm converges to the local minimum, the probability of escaping becomes less and less. *Id.* In simulated annealing, the random nature of the step choice and the conditional acceptance of poorer solutions theoretically allow the algorithm to escape local minima. *Id*. at ¶ 89. One variant of simulated annealing known in the art was fast simulated annealing (FSA). *Id*. at ¶ 91, Ex. 18 at 157-62. As Dr. Webb explained, “The faster cooling and hence shorter computational times (for fast simulated annealing) are allowed because the form of the Cauchy distribution generates occasional large grains which allow the system to tunnel out of a local minimum.” Ex. 22 at 62. One of skill in the art would have appreciated that by adding occasional large grains, FSA provides another way to escape from a local minimum. Rosen Dec. at ¶ 91.

Dr. Carol has explained in various contemporaneous publications how simulated annealing works in radiation treatment planning, *see e.g.*, Ex. 3 at 20:

> Iterative or stochastic methods, although slower, are able to move through a solution space (sometimes in a random manner) to find the global minimum. They are exemplified by simulated annealing which, as applied to radiation therapy treatment planning, proceeds by randomly changing beam weights, then evaluating the effect of each changed on the dose distribution. The acceptability of a change is determined by a cost function which is a mathematical quantification of how conflicting goals will be resolved; a higher cost is produced when the resulting dose distribution strays from the desired dose distribution. In general, although not always, the production of a higher cost results in throwing out of the change in beam weight (higher costs are occasionally accepted in order to allow escape from local minima). A lower cost usually results in accepting the change, and then proceeding to the next iteration. The iterative changing of beam weights continues until the cost reaches a user-designated acceptable level.

F. Beam weight optimization in radiation therapy

Optimization in radiation therapy is almost exclusively focused on finding the beam weights for each beamlet of each beam that together result in the best dose distribution for a patient. Rosen Dec. at ¶ 94. Although there have been research studies on using optimization to find the best beam geometry (number of beams and directions), this problem is extremely computationally intensive and impractical to solve. *Id*. at ¶ 95; Dkt. 131 at Ex. 4. In the mid 1990's, few people in the art were attempting to optimize beam orientations (i.e., beam geometry). Rosen Dec. at ¶ 95. Computers at that time did not have sufficient computing power to solve the geometry problem for real patients. *Id*.. Even today, there is little research on this problem because of the enormous computation demands. *Id*.

In radiation treatment planning, there are two basic conflicting goals. The goal for the target is a high dose to destroy the disease, but the goal for the normal tissues is a low dose to avoid radiation damage and the resulting treatment complications. *Id.* at ¶ 98. These conflicting goals can be implemented through the cost function in one of three ways: (1) the cost function may focus on delivering a high dose to the target and use constraints to limit the amount of radiation

to the normal tissues; (2) the cost function may focus on minimizing the doses to the normal tissues subject to constraints that force a minimum dose to the tumor; or (3) the cost function may include doses to both the target and normal structures and use weighting factors to drive the solution to the desired compromise.[4] *Id.* at ¶99. When the cost function includes both target and normal tissue doses, weighting factors (importance factors) are used to quantify the relative importance of each. *Id.* at ¶ 100. The final result of the optimization process is thus entirely dependent on the goals specified by the user, and the solution is optimal only for the goals defined by user through the input parameters and importance factors entered. *Id*. at ¶ 102. Changing those factors will lead to a different optimum solution. *Id*.

G. The '283 Patent

1. Public Disclosures of the Peacock and the Corvus System

Mark Carol, the principal inventor on the '283 patent, was the founder of NOMOS Corporation, which was subsequently acquired by BMI. In 1991, he began working on a treatment planning system called the Peacock, an unpatented precursor to the optimization system disclosed in the '283 patent. In a May, 1995 article (almost 18 months before the filing of the provisional application that led to the '283 patent), Dr. Carol disclosed to the public a treatment planning system that had nearly all of the elements of the purported invention claimed in Claims 25 and 29 of the '283 patent. Ex. 2 at 57-58. The Peacock system was based directly on Steve Webb's work. Dr. Webb published regularly, did not patent his inventions, and shared information freely with Dr. Carol and others. *See* Ex. 22 at 51:

> While this simulated annealing methodology is not exclusive to the NOMOS PEACOCK planning system to create suitable beam for implementation … the simulated annealing planning technique was the one chosen by NOMOS for this system and to the author's knowledge this represents the only commercial implementation to

---

[4] The '283 patent describes the third approach, using weighting factors applied to the zones of the CDVHs for both targets and structures. *See* col. 13:53-15-46.

> date by a radiation therapy manufacturer for external beam therapy planning. ***The implementation was based on original ideas published by the author*** but the commercial development was entirely independently carried out by NOMOS.

On May 17-18, 1996, five months before the ***provisional*** application was filed, Dr. Carol and his company, NOMOS, hosted the 1st NOMOS IMRT workshop conference in Durango, Colorado. In attendance and presenting papers were some of the foremost names in the radiotherapy field at that time, including Dr. Steve Webb, Dr. Isaac Rosen and others. Rosen Dec. at ¶ 108. Dr. Carol presented two papers, one on the precursor Peacock system, discussed above, and the second on the newly developed CORVUS system. *See* Ex. 2, 3. Dr. Carol explained the problems with early versions of IMRT systems that required multiple planning attempts before the "best" plan possible for a particular patient could be achieved. To solve this problem, Dr. Carol explained:

> In fact, a user-interface has been created for one such inverse planning system, CORVUS. ***CORVUS uses partial volume information for each structure out of which CDVH curves are generated and used as the goal by the optimizer***. For each target, the user enters: goal, minimum dose, maximum dose and percent volume which is allowed to be underdosed. For each structure, the user enters: desired limit, minimum dose, maximum dose and percent volume which can be greater than limit. The system creates CDVH curves for the targets and structures from these entries which are used by the optimizer as a representation of the desired dose distribution.
>
> * * * * *
>
> With any planning system, regardless of the type of prescription process required, the likelihood exists that all of the user's goals cannot be satisfied at the same time.… Since the cost function is 'responsible' for resolving such conflicts, *it is crucial that the cost function be predictable and understandable by the user; the user must know, at the time of prescription, whether the mug will be treated or the coffee spared.*
>
> *CORVUS uses a unique Area Cost Function which is explicit in its resolution of conflicts. After a CDVH is constructed from user-entered partial volume values, the system divides the CDVH into regions and automatically assigns a relative weight to each. These weights are used to resolve conflicts between the various CDVH regions defined by the target goals and structure limits.*

See Ex. 4 at 247; Ex. at 318, setting forth specific formulas for modified cost function. Thus more than five months before the filing of the *provisional* application, Dr. Carol apparently had disclosed to the public the "modified" cost function disclosed and claimed in the '283 patent.

2. The '283 Patent is A Narrow Improvement Patent

Viewed in this context, it is not surprising that the '283 patent specification refers to the invention as "an ***improved*** optimized treatment planning system," *see* col. 9, lines 49-50, emphasizes a "***modified*** cost function," *see* col. 9, line 52-53, and acknowledges that other than that ***modified*** cost function, everything in the '283 patent was known in the art, *see* col. 12, lines 34-45. At best, the '283 patent is a narrow improvement patent over the abundant prior art in the radiotherapy inverse planning optimization field based on the work of Dr. Webb and others. Every element of the claimed invention was known in the art, with the possible exception of the specific "modified" cost function which uses partial volume data input to create CDVH's, divides those CDVH's into zones, weights those zones differentially, and uses those parameters to find the cost of each proposed set of beam weights created by the simulated annealing algorithm.[5] Accordingly, the claims must be limited to the specific cost function and the specific optimization algorithm disclosed in the specification.

III. LEGAL PRINCIPLES FOR CLAIM CONSTRUCTION

A. *Phillips* Controls Claim Construction

Claim construction is much more than the simplistic exercise of determining what isolated claim terms mean out of context, relying on general dictionary definitions to do so. That approach, which results in overly broad claims untethered to the specification, was soundly rejected by the Federal Circuit in *Phillips.* Walking the "fine line" between reading the claims in

[5] Accuray reserves the right to challenge the validity of the asserted claims under 35 §§ U.S.C. 101, 02, 103, and 112.

light of the specification without improperly importing limitations into the claims from the specification has always been the challenge of claim construction. See *Phillips*, 415 F.3d at 1323 ("[U]pon reading the specification in context*, it will become clear whether the patentee is setting out specific examples of the invention to accomplish those goals, or whether the patentee intends for the claims and the embodiments to be strictly coextensive*. ") The court recently explained, "In reviewing the intrinsic record to construe the claims, ***we strive to capture the scope of the actual invention***, rather than strictly limit the scope of the claims to disclosed embodiments or allow the claim language to become divorced from what the specification conveys is the invention." *Retractable Technologies, Inc. v. Becton Dickinson and Co.*, 653 F.3d 1296, 1305 (Fed. Cir. 2011) (citing *Phillips*, 415 F.3d at 1323-24). As Judge Plager stated in his concurrence,

> I understand how a perfectly competent trial judge can be persuaded by the siren song of litigation counsel to give the jury wide scope regarding what is claimed. But it is a song to which courts should turn a deaf ear if patents are to serve the purposes for which they exist, including the obligation to make full disclosure of what is actually invented, and to claim that and nothing more.

Retractable Techs., 653 F.3d at 1311 (Plager, J. concurring).

B. The Court Must Construe Claims from the Perspective of One of Ordinary Skill in the Art

A claim term is generally given its "ordinary and customary meaning," that is, "the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention." *Phillips*, 415 F.3d at 1312-13. The person of ordinary skill in the art must read the claim term in the context of the claim, and in the context of the entire patent, using the knowledge of the field he or she has to understand the words of the claim. *Phillips*, 415 F.3d at 1313. The person of ordinary skill in the art is, of course, a legal construct, embodying a certain level of skill in the art. The factors to be considered in determining the level of ordinary skill in

the art include: (1) the educational level of the named inventor(s); (2) the type of problems encountered in the art; (3) prior solutions to those problems; (4) rapidity with which innovations are made; (5) sophistication of the technology; and (6) educational level of active workers in the field. *See Daiichi Sankyo Co. v. Apotex, Inc.,* 501 F.3d 1254, 1256 (Fed. Cir. 2007). Familiarity with all of the art in the field, even if that art was secret and would not have been known, is presumed. *See In re Rouffet*, 149 F.3d 1350, 1357 (Fed. Cir. 1998).

C. The Role of the Specification in Claim Construction

The court must always read the claims "in view of the specification, of which they are a part." *Phillips*, 415 F.3d at 1315. The specification is "the single best guide to the meaning of a disputed claim term," and, usually, the specification's use of a claim term is dispositive. *Phillips*, 415 F.3d at 1315. Moreover, "[t]he specification *acts as a dictionary* when it expressly defines terms used in the claims or when it defines terms by implication. Even when guidance is not provided in explicit definitional format, the specification may define claim terms by implication such that the meaning may be found in or ascertained by a reading of the patent documents." *Phillips*, 415 F.3d at 1321. Thus, the specification is "always *highly relevant* to the claim construction analysis." *Id.*

When the patentee uses descriptive terms such as "the present invention" to describe what is claimed, those descriptive embodiments may limit the claims. *See Honeywell International, Inc. v. ITT Indus., Inc.*, 452 F.3d 1312, 1318 (Fed. Cir. 2006) (court limited "fuel injection system component" to "fuel filter because all the disclosed embodiments disclosed only fuel filters and specification repeatedly described the fuel filter as "this invention" and "the present invention."); *Am. Piledriving Equip., Inc. v. Geoquip, Inc.*, 637 F.3d 1324, 1334 (Fed. Cir. 2011). Likewise, consistent use of a claim term in a specific way in the specification may limit otherwise broad language in the claim. *See Nystrom v. TREX Co.*, 424 F.3d 1136, 1145 (Fed. Cir. 2005); *Phillips*,

415 F.3d at 1316. The specification need not reveal such a definition explicitly. *See Bell Atl. Network Servs., Inc. v. Covad Commc'ns Group, Inc.*, 262 F.3d 1258, 1271 (Fed. Cir. 2001).

Similarly, the patentee's distinctions of the invention over the prior art may also define the claims. *Phillips* instructs courts to construe claims consistent with a "*full understanding of what the inventors actually invented*." *See Inpro II Licensing S.A.R.L. v. T-Mobile USA, Inc.*, 450 F.3d 1350, 1354-55 (Fed. Cir. 2006). The prior art cited in the patent is intrinsic evidence that is relevant to what one of skill in the art would have thought the claim terms meant at the time of invention. *Phillips*, 415 F.3d at 1317.

Claim differentiation "does not trump the clear import of the specification," *Eon-Net LP v. Flagstar Bancorp*, 653 F.3d 1314, 1323 (Fed. Cir. 2011). Limiting statements in the specification can rebut a broad claim term interpretation, even if the breadth of that term is reinforced by the doctrine of claim differentiation. *See Regents of the University of California v. Dakocytomation California, Inc.*, 517 F.3d 1364, 1375 (Fed. Cir. 2008).

D. Prosecution History is Also Relevant

In addition to considering the specification, courts should consider the relevant prosecution history of an asserted patent. *Phillips*, 415 F.3d at 1317. "[T]he prosecution history can often inform the meaning of the claim language by demonstrating how the inventor understood the invention and whether the inventor limited the invention in the course of the prosecution, making the claim scope narrower than it would otherwise be." *Id*.

E. Extrinsic Evidence Should Not Contradict the Intrinsic Record

Extrinsic evidence "consists of all evidence external to the patent and prosecution history, including expert and inventor testimony, dictionaries, and learned treatises." *Phillips*, 415 F.3d at 1317. The court may look to extrinsic evidence "to ensure that the court's understanding of

the technical aspects of the patent is consistent with that of a person of skill in the art." *AIA Eng'g Ltd. V. Magotteaux Int'l S/A*, 657 F.3d 1264, 1277 (Fed. Cir. 2011).

Expert testimony can be useful "for a variety of purposes, such as to provide background on the technology at issue, to explain how an invention works, [or] to ensure that the court's understanding of the technical aspects of the patent is consistent with that of a person of skill in the art . . . ." *Phillips*, 415 F.3d at 1318. The testimony of an inventor also may be pertinent as a form of expert testimony, such as to understand the established meaning of particular terms in the relevant art. *Id.*

Dictionary definitions may be used, but may not contradict the intrinsic record. *Id*. As evidenced by the *Texas Digital* era, reliance on dictionary definitions and the accompanying "heavy presumption" of plain meaning results in overly broad claim constructions untethered to the specification. *Phillips*, 415 F.3d at1321. ("The risk of systematic overbreadth is greatly reduced if the court instead focused at the outset on how the patentee used the claim term in the claims, specification, and prosecution history, rather than starting with a broad definition and whittling it down.")

IV. THE LEVEL OF SKILL IN THE ART

The level of skill in the field of radiation therapy planning, and particularly optimization in the mid-1990's was very high. Rosen Dec. at ¶¶ 18-19. One of ordinary skill in the art would have had a PhD in Physics, medical physics or a related science, at least five years of practical experience in radiation treatment planning, and at least several years of research in treatment plan optimization. *Id.*

V. PROPOSED CLAIM CONSTRUCTION FOR CLAIM 25

A. "Apparatus for determining an optimized radiation beam arrangement"

"Apparatus for determining an optimized radiation beam arrangement" means "a computer

configured to use the simulated annealing ("SARP") optimization algorithm to determine the optimal array of beam weights for the beam elements at each orientation based on the treatment objectives as expressed in the cost function incorporated in the SARP algorithm**."**

"Optimized radiation beam arrangement" means "the optimal array of beam weights for the beam elements at each orientation based on the treatment objectives as expressed in the cost function incorporated in the SARP algorithm**."**

1. The Intrinsic Record Supports Accuray's Construction

The specification uses the term "optimized radiation beam arrangement" consistently to mean "the optimal array of beam weights." The specification discloses that the "optimized beam arrangement" "should be understood to include ***either*** the optimal beam arrangements around the treatment field, ***the optimal array of beam weights***, or beam intensities, otherwise known as an intensity map or a fluence profile ***or both***. The specification, however, provides no disclosure of how to achieve "the optimal beam arrangements around the treatment field," commonly referred to by those of skill in the art as the beam geometry or orientation. *See* col. 9:29-40. The only reference to beams is found at col. 12:27-32 ("A SARP technique is utilized to do this optimization *by dividing the radiation delivery into a large number of small beams, each of which hit the target*.") Similarly, the Webb papers provide no disclosure of optimizing beam orientation or beam geometry, but rather focus exclusively on the *optimization of beam weights* using the simulated annealing algorithm. Webb simply notes that "the beams are to be arranged at appropriate orientations relative to the tumor volume and divided into beam elements at each orientation, and then states, "the problem then becomes *determining the optimum weights* for the beam elements at each orientation given the dose prescription," a problem is solved by the

method of simulated annealing ("SARP"). Ex. 4, Dkt 131 at 1350.[6]

The specification focuses solely on how to determine the "optimal" ***array of beam weights*** using SARP, and relies heavily on the purported incorporation by reference of the Webb articles on simulated annealing to do so. *See* col. 12:27-47. The optimal beam arrangement is arrived at *by computationally increasing the proposed beam weight iteratively*, incorporating cost functions to ensure that an iterative change in the beam weight would not result in an unacceptable exposure to the volumes of tissue or other structures being subjected to the proposed dose." *See* col. 9:29-40. The specification repeatedly states that the Simulated Annealing algorithm, referred to as "SARP," (a term coined by Dr. Webb), is used to determine an optimized beam arrangement. *See* col. 8:61-9:48. ("Simulated annealing radiotherapy algorithms ("SARP") methods are well known in the art to compute optimized radiation beam arrangements …. Existing SARP methods utilize systematic algorithms to calculate a proposed, optimized beam arrangement.") *See* col. 12:34-45 ("A SARP technique is utilized to do this optimization …. Except for the detailed description of the cost function utilized in the present invention, the details of the foregoing simulated annealing techniques are known in the art and described in such publications as [the Webb 1989 and 1991 articles], which publications are incorporated by reference.") The only optimization algorithm disclosed in the specification is the simulated annealing algorithm ("SARP"). In fact, the specification uses the words "simulated annealing" at least twenty times and "SARP" at least six times. The specification refers to the Fast Simulated Annealing variant (FSA) of the simulated annealing algorithm as the preferred embodiment. *See* col. 12:30-47. The specification provides no disclosure of any optimization

[6] If the "optimized radiation beam arrangement" is construed to include beam geometry in addition to beam weights, the claims would be invalid under 35 U.S.C. 112, ¶ 1 for lack of written description and lack of enablement.

algorithm *other than the simulated annealing algorithm*, and relies on Webb for the only detailed disclosure of how SARP optimizes beam weights. *See* Col. 12:27-47.

The specification further treats "optimized" as a relative term, dependent on the particular optimization algorithm and input parameters used. *See* col. 9:45-49 ("[T]he SARP method will produce an optimized treatment plan, *based on the treatment objectives as expressed in the SARP algorithm*.") (emphasis added). The specification discloses particular input parameters and a specific cost function that are used by the simulated annealing algorithm to arrive at an optimized array of beam weights. *See* col. 12:48-14:10. *See* detailed discussion below.

The specification confirms by its consistent use of the term "optimal radiation beam arrangement" to mean an "array of beam weights based on the treatment objectives as expressed in the cost function incorporated in the SARP algorithm" that the claim term should be so limited. *See, e.g., Nystrom*, 424 F.3d at 1145; *Bell Atl. Network Servs., Inc.,* 262 F.3d at 1271.

The only apparatus disclosed in the specification for determining this optimized radiation beam arrangement is a computer configured with and running plan optimization software that includes the simulated annealing algorithm. *See* col. 12:45-47 ("A suitable computer is utilized in performing the Plan Optimization Step…."); col. 9:59-64 ("The optimization method may be carried out using conventional equipment, including … a conventional computer or set of computers, and plan optimization software, which utilizes the optimization method of the present invention."); col. 13;53-15:46; col. 8:67-9:27. Although other equipment is disclosed in the specification for treatment delivery (*e.g.,* the linear accelerator and the patient couch), this equipment is not necessary for optimizing beam weights.

The prosecution history is in accord. The Examiner required the applicant to amend the claims to include "changing the beam weights" limitation in every claim, consistent with the

understanding that the optimized radiation beam arrangement is an array of beam weights, and does not include beam geometry or orientation. *See* Office Action dated 2/16/99; Amendment dated 5/17/99.

2. Extrinsic Evidence Further Supports Accuray's Construction

At the time of filing, one of skill in the art would have understood, in light of the specification and his or her knowledge in the field, that the asserted claims are limited to an apparatus for determining the optimization of beam weights using the simulated annealing algorithm. Further, the apparatus necessary for optimizing beam weights is a computer configured with and running optimization software including the simulated annealing algorithm. Simulated annealing methods had been used for a number of years to optimize beam weights, and of the many variants of simulated annealing, including Fast Simulated Annealing. Rosen Dec. at ¶ 87, 91; Ex. 19 at 179-80. Skilled artisans knew of the advantages associated with simulated annealing, including its relative simplicity and the fact that it was "well-suited for complex many-dimensional cost functions." *Id*. In contrast, skilled artisans appreciated that the optimization of beam orientation was an intractable problem, and that no one had come up with a solution. Rosen Dec. at ¶ 94-95. Beam orientation optimizations were too complex and computers did not have sufficient computing power to tackle the problem. *Id.*

Those of skill in the art also understood that "optimized" was a relative term, dependent on the optimization algorithm, the input parameters, and the particular cost function used. Ex. 2 at 58 ("The degree to which a treatment plan is 'optimized' is in part determined by constraints placed on the planning algorithm.").

3. BMI's Construction is Divorced from the Intrinsic Record

BMI's constructions resurrect the outdated *Texas Digital* approach to claim construction that was expressly repudiated by the Federal Circuit in *Phillips*. Ignoring context, BMI proffers a

generic construction of "apparatus," relying on an English language dictionary published two years after the patent issued. BMI reads the claim as if it were directed to an entire Treatment Planning System, or a radiation therapy system that includes both treatment planning and delivery, but to one skilled in the art, even a cursory review of the specification reveals that the '283 patent is directed to optimization of beam weights, which is just one aspect of a radiation Treatment Planning System. The written description repeatedly characterizes "the invention" as a narrow improvement over the art that uses a known optimization algorithm ("SARP") and a "modified" cost function defined in the specification. The claims are thus limited to that "characterization of the invention." *See Honeywell*, 452 F.3d at 1318. *See also Andersen Corp. v. Fiber Composites, LLC*, 474 F.3d 1361, 1367-68 (Fed. Cir. 2007); *Microsoft Corp. v. Multi-Tech. Sys., Inc*., 357 F.3d 1340, 1348 (Fed. Cir. 2004); *Alloc, Inc. v. Int'l Trade Comm'n*, 342 F.3d 1361, 1370 (Fed. Cir. 2003).

BMI argues throughout its brief that the claims are not limited to simulated annealing, based on the doctrine of claim differentiation. Claim differentiation, however, is simply "a rule of thumb that does not trump the clear import of the specification," *Eon-Net LP,* 653 F.3d at 1323. "The doctrine of claim differentiation cannot broaden claims beyond their correct scope, determined in light of the specification and the prosecution history and any relevant extrinsic evidence." *MarTec LLC v. Johnson & Johnson*, 664 F.3d 907, 918 (Fed. Cir. 2012). The asserted apparatus claims do not have dependent claims which add a limitation of simulated annealing. *See Anderson*, 474 F.3d at 1369-70 (declining to apply claim differentiation where there were other differences between the claims).

B. "A computer adapted to computationally obtain a proposed radiation beam arrangement"

"**A computer**" means "the specific computer that performs the beam weight optimization."

That computer is configured with and running plan optimization software, including the simulated annealing algorithm, which performs the beam weight optimization.

"**Adapted to computationally obtain**" means "configured to run the Simulated Annealing algorithm ("SARP") to calculate 'a proposed radiation beam arrangement.'" The computer is loaded with and runs plan optimization software that includes the simulated annealing algorithm to calculate "a proposed radiation beam arrangement."

"**A proposed radiation beam arrangement**" means "an array of proposed beam weights for the beam elements at each orientation calculated using the simulated annealing ("SARP") algorithm during a given iteration of the simulated annealing ("SARP") algorithm from the partial volume data input by the user for each target and structure."

1. The Intrinsic Record Supports Accuray's Construction

The specification repeatedly refers to a specific computer that is running optimization software to perform the optimization of beam weights. *See, e.g.,* col. 12:45-47 ("A suitable computer is utilized in performing the Plan Optimization Step."); col. 6:24-43. The specification further discloses that the optimization algorithm used to optimize beam weights is a "computational method." *See* Col. 3:17-52 ("Existing methods and apparatus utilize a *computational method* of establishing optimized treatment plans based on an objective cost function…."). The specification consistently refers to only one specific computational method, simulated annealing ("SARP"). *See id.* ("*One such computational method is known in the art as simulated annealing.*") The Webb articles refer to simulated annealing ("SARP") as a computational method for optimizing beam weights. *See e.g*., Dkt. 131 at Ex. 4, p. 1352**:** (**"**In other contexts simulated annealing has been shown to be *more computationally efficient* than a direct search for the global potential minimum….").

The specification consistently discloses that the proposed radiation beam arrangement is

calculated using the simulated annealing algorithm or "SARP." *See* col. 5:1-3: ("[T]he proposed radiation beam arrangement may be calculated using simulated annealing radiation therapy planning methods."); Col. 8:61-67. Indeed, the specification provides no disclosure of any optimization algorithm ***other than*** the simulated annealing algorithm. The specification itself provides no details of how the simulated annealing algorithm optimizes beam weights, but instead relies on the Webb articles to provide the only detailed disclosure. *See* Col. 12:27-47. Indeed, without the Webb references, there is insufficient disclosure to describe or enable the use of any optimization algorithm.

The specification repeatedly refers to "a proposed radiation beam arrangement" as "*proposed during a given iteration*." *See, e.g*., Col. 5:9-47: ("using a computer to iteratively compare a cost of a *radiation beam arrangement proposed during a given iteration to a beam arrangement proposed during the previous iteration* …."); Col. 5:49-60: ("In accordance with another aspect of the invention. … (1) determining a CDVH associated with each target and structure based on the *proposed radiation beam arrangement of a given iteration*…."); col. 5:48-6:20. This disclosure is consistent with how simulated annealing optimizes beam weights.

The specification further discloses that the proposed radiation beam arrangement (like the "optimized radiation beam arrangement") is an array of beam weights, and does not include beam geometry. *See* col. 9:29-40; col. 12:27-47. *See* discussion above regarding lack of disclosure of beam geometry or orientation. At each iteration of the simulated annealing algorithm, a proposed radiation beam arrangement or set of beam weights is generated by randomly adding beam weight to beamlets or beam elements. The only disclosure of how this proposed array of beam weights is obtained is found in the Webb articles:

> In the context of treatment planning the aim is to 'grow' the beam weight sonogram slowly (i.e., *iteratively, in steps*) and optimize the consistency between the dose

> distribution that this would spawn and the dose prescription. The technique will begin with all beam weights set to zero and 'grains' of beam weight are offered at random to the beam elements. The term 'grain' implies a small quantum in the sense that the beam elemental weights which are arrived at comprise a large number of such quanta. At each offering the dose distribution, resulting from the current ensemble of beam elemental weights, is compared with the prescription and if the attempt at grain placement were to lead to a greater correspondence it is accepted and generally vice versa…. In essence, the aim is to minimize the difference between the two.

See Dkt. 131 at Ex. 4, pp. 1352-56; Dkt. 131 at Ex. 5, pp. 1228-29.

The specification provides a detailed disclosure of the input parameters used by the optimization software to generate a proposed radiation beam arrangement at each iteration of the simulated annealing algorithm and determine whether it will be accepted. The user enters certain input parameters (partial volume data) into the Prescription Panel which represent the desired goal. *See* Fig. 5A; Col. 10:31-33. The partial volume data (defined below), are used to generate CDVH curves for each target and structure of the patient. *See* Fig. 5B; Col. 10:53-11:8:

> The CDVH curves 100, 200 utilized in the system of the present invention are created from partial volume data for each target and structure of a given patient. In the system of the present invention, partial volume data are entered by the user during the Prescription Panel step 802 (FIG. 2). FIG. 5 shows an embodiment of a prescription panel 400 used to input the partial volume data into the planning system of the present invention. The partial volume data generally describes what percent of the volume of a tumor or structure can receive how much dose.

The partial volume data for the target and each critical structure, and the CDVH curves that are generated from the partial volume data, are input parameters for the cost function that is incorporated into the simulated annealing algorithm. *See* Col. 10:35-52:

> In contrast, the familiar CDVH curves 100, 200 are used by a physician using *the system of the present* invention not only in the Output Process step 807 (FIG. 2) … but also prior to the Plan Optimization step 803 (FIG. 2) *to establish partial volume data representing dosage limits and other parameters … for each target and structure to establish the input parameters for the cost function of the present invention, which may be entered in the Prescription Panel step 802 (FIG. 2) of the present invention.*

See also, Figs. 2-5; Col. 11:8-12:20; Col. 12: 21-26. The specification discloses that CDVH

curves for the target and each critical structure are divided into zones based on the partial volume data points, and each zone is weighted differentially depending on whether the user considers the target or the structures to be more important. *See* Col. 12:48-67; Col. 13:53-14:10; Col. 15: 5-15; Col. 15:16-46. The prosecution history further supports the construction of "proposed radiation beam arrangement" to mean an array of beam weights. *See* File History: Office Action dated 2/16/99; Amendment dated 5/17/99.

2. Extrinsic Evidence Further Supports Accuray's Construction

One of skill in the art would have appreciated that the asserted claims are directed specifically to optimization of beam weights, not to optimization of beam geometry. *See* Webb 1989, above. A skilled artisan would have understood that the computer adapted to computationally obtain a proposed array of beam weights is limited to a computer configured with and running plan optimization software, including the simulated annealing algorithm. The only optimization algorithm disclosed in the specification was simulated annealing, and that no other optimization method is disclosed. Id. at ¶ 121. Further, to use an optimization algorithm other than simulated annealing would have required additional experimentation. *Id*. at ¶ 127.

Based on Webb, the skilled artisan would have understood that the proposed set of beam weights was obtained by running the simulated annealing algorithm. *Id.* at ¶ 121. At each iteration of the simulated annealing algorithm, a new proposed set of beam weights is obtained by randomly adding or subtracting small grains of beam weight. *Id.* at ¶ 123. Further, the Webb articles provide the only disclosure of how that set of beam weights is obtained from the specific input parameters disclosed in the specification. *Id.* at ¶ 121. Accordingly, the skilled artisan would have understood that the proposed radiation beam arrangement is a proposed array of beam weights at a particular iteration of the simulated annealing algorithm.

Contemporaneous publications by the principal inventor, Mark Carol, support Accuray's construction. Dr. Carol used the same optimization algorithm, simulated annealing (FSA), to optimize beam weights in the prior art Peacock system. *See, e.g.*, Ex. 2 at 57. Dr. Carol's publications also confirm that one of skill in the art would understand "proposed radiation beam arrangement" to mean a proposed array of beam weights generated at an iteration of the simulated annealing algorithm. *See id.*.

3. BMI's Construction is Divorced from the Intrinsic Record

BMI again ignores context, arguing that the term "computer" should be given a "plain and ordinary" meaning that would cover virtually any computer (a general purpose computer). BMI's construction is not based on any technical understanding of the '283 patent by one skilled in the art, but rather on a generic definition plucked from an English language dictionary. Moreover, BMI's construction ignores the functional language modifying the term "computer," which makes clear that the computer must be one that is: "adapted to computationally obtain a proposed radiation beam arrangement," "further adapted to computationally change the proposed radiation beam arrangement iteratively," "further adapted to incorporate a cost function . . . ," and "further adapted to reject . . . and to accept." *See* Claim 25. The computer "adapted to" perform each of these functions must be a specific computer configured to run and running optimization software including the simulated annealing algorithm, the ***only*** optimization algorithm described in the specification.

BMI asserts that the term "proposed" means "suggested" and that "radiation beam arrangement" means "beam positions around a treatment field ***and/or*** an array of beam weights, intensities or fluence profiles." The specification, however, repeatedly refers to "a proposed radiation beam arrangement" as "proposed during a given iteration" of the SARP algorithm. Further, BMI concedes that the term "proposed radiation beam arrangement" could mean "an

array of beam weights." The specification does not disclose optimization of beam geometry, and the state of the art at the time the '283 patent was filed supports that construction. *See* Rosen Dec. at ¶ 194-96. Here, the patentee chose to claim only the optimization of beam weights. In the absence of any disclosure regarding beam geometry, BMI's alternate construction would render the '283 patent invalid under 35 U.S.C. § 112 for lack of written description and/or lack of enablement. *See* 35 U.S.C. § 112 ¶1; *Ariad Pharms., Inc. v. Eli Lilly and Co.,* 598 F.3d 1336, 1351 (Fed. Cir. 2010).

C. The Computer Further Adapted to Computationally Change the Proposed Radiation Beam Arrangement Iteratively, wherein the proposed radiation beam arrangement is changed by changing the beam weights"

"Further adapted to computationally change the proposed radiation beam arrangement iteratively" means "configured to run the Simulated Annealing algorithm ("SARP") to change 'the proposed radiation beam arrangement' (defined above) by adding or subtracting beam weights to beam elements randomly at each iteration (or each cycle) of the SARP algorithm."

"Further adapted to" means: configured to run the same optimization algorithm as above, the simulated annealing algorithm ("SARP"). See discussion above regarding "a computer adapted to." **"**Computationally change" means using the simulated annealing algorithm ("SARP") to add or subtract beam weight to the beam elements randomly. *See* analysis above for "computationally" and construction of "proposed radiation beam arrangement." "Iteratively" means in cycles of the simulated annealing ("SARP") algorithm. "Changing the beam weights" means "adding or subtracting small quanta of positive and negative beam intensities to the beam elements randomly at each iteration of the simulated annealing ("SARP") algorithm." The amount of beam intensity added to each beam element is referred to in the intrinsic record variously as "quantum," "grain," or "amount." "Beam weights" means "beam intensities."

1. The Intrinsic Record Supports Accuray's Construction

As discussed above, the recited computer is running optimization software that includes the simulated annealing algorithm. Simulated annealing ("SARP") is the only optimization algorithm disclosed in the specification. *See, e.g.*, col. 12:27-34. The specification discloses that the optimal beam arrangement is arrived at by changing the proposed array of beam weights at each iteration of the simulated annealing algorithm. *See* Col. 9:29-49 ("The optimal beam arrangement is arrived at iteratively by increasing [or decreasing] the proposed beam weight iteratively…."). The specification further emphasizes that, except for "the cost function utilized in the present invention," *the details of the simulated annealing techniques are known in the art*, and are described in the Webb articles incorporated by reference. *See* col. 12:34-47; col. 13:40-52; col. 13:53-14:4; col.15:5-46. Thus the only disclosure of how the simulated annealing algorithm works to change the proposed radiation beam arrangement iteratively is found in the Webb publications. Dkt. 131 at Ex. 4, pp. 1352-56. Webb further explains that beam weights are beam intensities. "The [simulated annealing optimization] technique is iterative…. The method proceeds by *adding 'grains of beam intensity'* randomly to beam elements…. *Grains are small elements of beam intensity, randomly positive and negative.*" Dkt. 131 at Ex. 5, pp. 1227-29. The prosecution history further supports Accuray's construction. See Office Action dated 2/16/99; Amendment dated 5/17/99.

2. Extrinsic Evidence Further Supports Accuray's Construction

One of skill in the art of would have understood that the proposed array of beam weights is changed at each iteration of the simulated annealing algorithm by adding or subtracting random small amounts (grains) of beam weight. Rosen Dec. at ¶ 123. Unlike analytic methods such as linear programming algorithms, simulated annealing is an iterative stochastic method that proposes a new beam weight solution at each iteration. *Id.* at ¶¶ 79, 88, 93; Ex. 3 at 20. The cost

function incorporated in the simulated annealing algorithm measures the cost of the changed beam weights to determine whether the proposed solution is better or worse than the previous accepted solution. *Id*. at ¶ 93. The Fast Simulated Annealing variant disclosed in the specification has shorter computational times, and adds occasional large grains, which allows escape from a local minimum without the need for accepting a conditionally worse solution. *See* Ex. 4 at 62; Rosen Dec. at ¶ 91.

Dr. Carol's contemporaneous publications confirm how one of skill in the art would understand the claim term "changing the proposed radiation beam arrangement iteratively."

> The iterative approach to solving the optimization problem involves iteratively changing the strengths of the individual beamlets until a satisfactory solution is achieved…. Iterative systems typically require the user to assign graded weights and priorities to the structures and targets. By adjusting the relative weightings of the target and the surrounding structures, the planning systems will generate plans that vary greatly in the degree to which sensitive structures are spared and high dose lines conform to the three dimensional target contour. Ex. 2 at 57.
>
> Peacock Plan starts with the desired dose distribution and works in reverse *to generate the beam weights* needed to produce this distribution. Peacock uses *a so-called fast simulated annealing process to determine a set of beam weights….The iterative planning process for changing beam weights* is driven by a cost function – the higher the cost associated with a particular change in beam weights, the less likely the system is to retain the change.
>
> Iterative or stochastic methods … are exemplified by simulated annealing, which as applied to radiation therapy treatment planning, *proceeds by randomly changing beam weights*, then evaluating the effect of each change on the dose distribution…. The *iterative changing of beam weights* continues until the cost reaches a user-designated acceptable level. Ex. 3 at 20:

One of skill in the art would have understood that beam weights means "beam intensities." Rosen Dec. at ¶ 62. One of skill in the art would have understood that beam weights, although related to dose, are not equivalent to dose. *Id.* at ¶ 116. By changing the beam weights at a particular iteration, a new proposed radiation beam arrangement would be generated. The change of beam weights at a particular iteration results in a new proposed radiation beam

arrangement for that iteration, or a new proposed solution for that iteration. Id. at ¶ 123; Dkt 131, Ex. 4 at 1352. Proposing a new solution at each iteration is consistent with how iterative, stochastic algorithms like simulated annealing work. Rosen Dec. at ¶ 88, 93.

3. BMI's Construction is Divorced From the Intrinsic Record

BMI asserts that the phrase "change the proposed radiation beam arrangement iteratively" means "changing (altering, varying or modifying) the proposed radiation beam arrangement repeatedly." BMI's construction ignores the import of the term "iteratively," which is a hallmark characteristic of simulated annealing, the ***only*** optimization algorithm described in the specification. Dkt. 131 at Ex. 5, pp. 1227-29. In fact, the only disclosure of "changing the proposed radiation beam arrangement iteratively" is in the Webb articles. Dkt. 131 at Ex. 4, pp. 1352-56. The patentees ***chose*** to use Dr. Webb's language in the specification (quoting him verbatim in portions of the specification). Further, the patentees ***chose*** to use claim language that mirrors Dr. Webb's description of simulated annealing (*e.g*., the claim terms "iteratively," "greater correspondence"). BMI's attempt to disavow Webb's teachings now to obtain a broader claim construction should be rejected.

BMI construes the phrase "changing the beam weights" to mean "changing (altering, varying or modifying) the beam intensities or dose." BMI's construction again reveals a lack of understanding of its technology. Beam weight refers to the beam intensity of a beamlet as it is emitted from the MLC, whereas dose is the amount of radiation absorbed by the structure volume. Rosen Dec. ¶ 62. BMI quotes Kilby, but fails to understand its import. The excerpt refers to the end result of optimization. The optimized set of beam weights as delivered to the patient would result in a dose distribution, the beam weights of each beamlet that are changed during an iteration of simulated annealing do not correspond to a dose. *Id.* at ¶¶ 45-48.

D. "The computer further adapted to incorporate a cost function at each

iteration …to partial volume data associated with a pre-determined desired dose prescription"

"Further adapted to incorporate a cost function at each iteration" means: "the computer configured to run the simulated annealing ("SARP") algorithm incorporates a 'cost function' in each cycle of the SARP algorithm." See discussion above for "the computer adapted to….

"**At each iteration**" means "at each cycle of the simulated annealing ('SARP') algorithm." *See* support above, for "changing the proposed radiation beam arrangement *iteratively*."

"**Cost function**" means the cost function defined at column 13, lines 4-39, including each of the steps described therein:

> In the cost function of the present invention, each region or zone, of the CDVH is assigned a relative weight, according to the importance of that region, or zone of the CDVH. A zone cost is then calculated for the target and each structure according to the following formula:
>
> $C_z=W_z*(Ap/Ad)$,
>
> After each zone cost is calculated, the target or structure cost is calculated for each target or structure, according to the following formula:
>
> $CT= \Sigma Cz1 + Cz2 + Cz3 +. . . Czn$, and
>
> $CS= \Sigma Cz1 + Cz2 + Cz3 +. . . Czn$,
>
> The total cost for the change to the proposed beam distribution is then calculated, according to the following formula:
>
> $CTotal =CS+CT$, where CTotal is the total cost of the proposed change to the beam distribution."

Partial volume data (defined below) for each target and each structure are input parameters for the cost function entered by the user for determining the proposed radiation dose distribution to a patient. The cost function measures the total dosage cost of the change to the proposed radiation beam arrangement, or the difference between the proposed radiation beam arrangement and the pre-determined desired dose prescription.

To approach correspondence means: The cost function calculates a total dose cost for the

change to the proposed radiation beam arrangement which is a metric for how close the partial volume data (or CDVHs) of the proposed radiation beam arrangement of the current iteration is to the partial volume data (or CDVHs) of the desired dose prescription. The partial volume data and CDVH's are for the target and each involved structure. To approach correspondence means minimizing the difference between the proposed radiation beam arrangement and the desired dose prescription.

"**Partial volume data"** means: "numerical values corresponding to values represented as specific data points on CDVH curves associated with each target and each involved structure." Partial volume data are specific data points that are sufficient to generate a CDVH curve.

"Partial volume data associated with the proposed radiation beam arrangement" means: "Numerical values corresponding to values represented as specific data points on CDVH curves associated with each target and each involved structure based on the proposed radiation beam arrangement, which data points define the CDVH curves and the proposed zones incorporated in the cost function; generated within a given iteration of the simulated annealing ("SARP") algorithm."

"Partial volume data associated with predetermined desired dose prescription" means**:** Numerical values corresponding to values represented as specific data points on CDVH curves for each target, including at least: the minimum dose to be received by any portion of the target volume that will be underdosed [A],the desired dose to be achieved in the target volume [Bd], the portion of the target volume which should have a dose greater than the goal [Bv], and the target maximum dose value to be received by any portion of the target [C], and for each structure, including at least the desired dosage limit not to be exceeded in the volume of a sensitive structure [Bd']; the maximum dose to be received by any portion of the structure [C'] ;

the dose below which there is no appreciable benefit gained by reducing the exposure to the structure [A']; and the portion of the structure volume which can have a dose greater than the goal dosage may be represented by structure percent over limit value [Bv']; which data points define the CDVH curves and the zones incorporated in the cost function. Partial volume data are input into the prescription panel and associated with the predetermined desired dose prescription.

1. The Intrinsic Record Supports Accuray's Constructions

a) Further Adapted to Incorporate a Cost Function At Each Iteration

By its consistent references to the specific cost function disclosed in Column 13 as the "cost function of the present invention," the specification confirms Accuray's construction. *See Honeywell,* 452 F.3d at 1318 (claim limited to disclosed embodiments where specification repeatedly described embodiment as "this invention" and "the present invention.") *See, e.g.*, col. 13:4-5; col. 15:42-46. The specification further states that, "The ***cost function of the present invention*** may be easily incorporated into existing SARP algorithms by one skilled in the art." *See* col. 15:42-46; col. 12:27-47. No other cost function (and no other optimization algorithm) is disclosed in the specification.

Moreover, the specification repeatedly refers to the specific cost function disclosed at column 13 as the only aspect of the disclosure that is not known in the art. *See* col. 12:34-45 ("Except for the foregoing detailed description of the cost function utilized in the present system, the details of the foregoing simulated annealing techniques are known in the art …."). *See* col. 9:49-64 (The ***improved*** optimized treatment planning system … includes a ***modified cost function***, which allows a physician to use conventional cumulative dose volume histographs ("CDVH"s) to establish a desired prescription of dosage to both the target volume, or target, and each involved structure volume, or structure, which will then be used as input for the system for

determining the proposed radiation dose distribution for delivery to a patient.") As clearly stated in the specification, the improvement, if any, in the '283 patent, is the addition of a *modified* cost function incorporated into the well-known simulated annealing algorithm. Support for this construction is also found in the specification's explanation of the problem with prior art cost functions used with simulated annealing to determine optimized beam weights. *See* Col. 3:17-52. The specification purportedly provides a solution with the "modified" cost function disclosed in Column 13. *See* Col. 9:49-59 (emphasis added).

The only detailed disclosure found in the specification is that of the "modified" cost function and the specific input parameters for that cost function (the partial volume data used to generate CDVH curves for each target and structure, those CDVH curves divided into zones, and the differential weighting factors for those zones depending on the user's desired outcome). *See* col. 12:21-26; 12:48-67; 13:53-14:45. The specification explains how the cost function of the present invention is obtained. *See* col. 4:33-66:

> The cost function may be obtained by the steps of: determining a CDVH associated with the desired dose prescription; assigning zones to each CDVH; assigning weights to each zone, applicable to the CDVHs associated with both the desired dose prescription and the proposed radiation beam arrangement; calculating a zone cost for each target or structure… and calculating a total cost for the change in the proposed radiation beam arrangement [according to the disclosed formulas].

See also, col. 5:15-47; col. 5:48-8:28; col. 12:48-67; col. 13:1-39. The specification discloses that depending on how the different zones of the CDVH curves are weighted (with weighting factors), very different results can be obtained and must be incorporated into the software with an outcome in mind. *See* col. 13:53-59; col. 13:53-15:46.

The specification's explanation of the purpose of the cost function also supports Accuray's construction. See col. 9:29-49:

> The optimal beam arrangement is arrived at by computationally increasing the proposed beam weight iteratively, *incorporating cost functions to ensure that an iterative change in the beam weight would not result in an unacceptable exposure to the volumes of tissue or other structures* being subjected to the proposed dose. At each iteration, the dose distribution resulting from the proposed beam selection is compared to a prescribed dose for the tumor volume and surrounding tissue structures. If the increase or decrease in beam weights would lead to a greater correspondence to the desired prescription, the change is accepted. Ultimately, the SARP method will produce an optimized treatment plan, *based on the treatment objectives as expressed by the cost function incorporated in the SARP algorithm*.

The details of how the simulated annealing algorithm incorporates a cost function at each iteration are explained in Webb. The Webb 1989 article, at 1227-29, generally states,

> The [simulated annealing optimization] technique is iterative…. The method proceeds by adding 'grains of beam intensity' randomly to beam elements…. The decision whether to accept or reject the additions follows from inspecting the sign of the change in the cost function….

b) Partial volume data associated with the predetermined desired dose prescription

The specification discloses that the partial volume data are numerical values representing dosage limits and other parameters for each target and structure that are input into the Prescription Panel by the user, and used to generate CDVH curves. *See* col. 10:35-52:

> The *CDVH* curves 100, 200 utilized in the system of the present invention *are created from partial volume data for each target and structure of a given patient*. In the system of the present invention, partial volume data are entered by the user during the Prescription Panel step 802 (FIG. 2)….The partial volume data generally describes what percent of the volume of a tumor or structure can receive how much dose.

The specification also consistently uses the term "partial volume data" interchangeably with "CDVH." In other words, the partial volume data can be used to construct a CDVH or the CDVH can be used to generate partial volume data. *See, e.g.,* Col. 5:3-8; col. 6:43-46; Col. 7:4-5; 7:29-30 ("The partial volume data may be represented as a CDVH."); col. 7:66-8:14; Claim 1. The partial volume data entered by the user must be sufficient to generate a CDVH for each target and each involved structure.

The specification further discloses that these partial volume data are input parameters for the cost function incorporated into the simulated annealing algorithm. *See* Col. 10:35-11:8:

> In contrast, the familiar CDVH curves are used by a physician using the system of the present invention … prior to the Plan Optimization step 803 (FIG. 2) *to establish partial volume data representing dosage limits and other parameters … for each target and structure to establish the input parameters for the cost function of the present invention*, which may be entered in the Prescription Panel step 802 . . . .

The specification discloses the minimum partial volume data for a target and a structure to generate a CDVH curve, including for a target: dose goal, maximum dose for any portion of the target, minimum dose for any portion of target; and for a structure: the dosage limit for any portion of a structure, maximum dose and minimum dose. *See* col. 10:53-11:8; col. 11:9-26; col. 12:21-26; col. 11:36-51. The predetermined desired dose prescription encompasses the clinical goals the user has, as exemplified by the partial volume data. *See* col. 10:53-11:35.

c) Partial volume data associated with proposed radiation beam arrangement

The partial volume data associated with the proposed radiation beam arrangement is generated at each iteration of the simulated annealing algorithm. The disclosure in the specification regarding this phrase is in reference to the CDVH curves. *See* Col. 5:9-47 ("the costs being calculated by: (1) *determining a CDVH associated with each target and structure based on the proposed radiation beam arrangement of a given iteration*…"); col.5:48-6:20 ("*creating a proposed CDVH for each of the at least one target or structure, representing the cumulative effect of the proposed radiation beam arrangement*…."); see Claim 14 ("*determining a CDVH associated with each target and structure based on the proposed radiation beam arrangement of a given iteration*…"); Claim 18 ("*creating a proposed CDVH for each of the at least one target or structure, representing the cumulative effect of the proposed radiation beam arrangement*…."); see col. 6:23-7:30; col. 9:29-59; col. 10:35-12:26; 12:48-15:46; 13:1-52.

d) To approach correspondence of partial volume data associated with the proposed radiation beam arrangement with partial volume data associated with the desired dose prescription

The specification discloses that at each iteration of the simulated annealing algorithm, the cost function compares the CDVHs (partial volume data) for each target and structure associated with the predetermined desired dose prescription with the CDVHs (or partial volume data) for each target and structure associated with the proposed radiation beam arrangement. In other words, the cost function measures how close the CDVH (or partial volume data) of the proposed radiation beam arrangement for each target and structure of the current iteration is to the CDVH (or partial volume data) of the desired dose prescription. *See, e.g*., Claim 1 ("incorporating a cost function at each iteration to approach correspondence of a CDVH associated with the proposed radiation beam arrangement to a CDVH associated with a predetermined desired dose prescription."); col. 9:29-49. The idea is to minimize the difference between the CDVH's for each target and structure. Dkt. 131 at Ex. 4, pp. 1352.

Although much of the specification is written at the level of a clinician, and speaks in terms of visually comparing CDVHs to CDVHs, the underlying mathematics of the operation of the cost function is much more complex. The specification explains that the cost function calculates the total cost of the change to the beam weights according to the formulas disclosed in column 13. The cost for a proposed array of beam weights at a particular iteration of the simulated annealing algorithm, as stated above, is calculated based on the input parameters and by the formulas disclosed in column 13. The CDVH for each target and structure is generated from the partial volume data entered by the user. *See, e.g.,* FIGS. 5A, 5B. Each CDVH is divided into zones based on the partial volume data points entered. *See, e.g.,* FIGS. 3, 4. Each zone of the CDVHs for both target and structures is differentially weighted depending on the user's desired

outcome. *See* col. 13:53-15:46. The total cost of the change to the beam weights is then calculated for the target and each structure. *See* col. 13:4-52.

The cost measures the difference between the CDVH or partial volume data for each target and structure of the proposed radiation beam arrangement and the CDVH or partial volume data for each target and structure of the desired dose prescription. *See* col. 5:9-47:

> using a computer to iteratively compare a cost of a *radiation beam arrangement proposed during a given iteration to a beam arrangement proposed during the previous iteration* … the costs being calculated by: (1) determining a CDVH associated with each target and structure based on *the proposed radiation beam arrangement of a given iteration*; (2) assigning cost zones to the desired CDVH and the *proposed CDVH of a given iteration* associated with each target and structure; (3) assigning a weight value to each cost zone of each CDVH associated with each target and structure; (4) for each target and structure, multiplying the weight value of each zone by the quotient of a value representing the area of the zone of the CDVH associates with the proposed radiation beam arrangement and a value representing the area of the zone of the CDVH associated with the desired radiation beam arrangement; (5) summing the results of step (4) for each zone of each target and structure to obtain a total dosage cost ….

2. Extrinsic Evidence Further Supports Accuray's Construction

a) Cost Function At Each Iteration

One of ordinary skill in the art at the time would have understood the cost function claimed in the patent is the specific cost function disclosed at column 13. Rosen Dec. at ¶ 124. One of skill in the art would not have understood this term to mean any cost function because a variety of cost functions had been used with variants of the simulated annealing algorithm (and other algorithms) to optimize beam weights. Indeed, "The power of simulated annealing lies in the potentially infinite flexibility of choice of cost functions." *See* Ex. 22 at 60. And the "computation of the cost function is at the heart of the iterative solution." *Id*. Thus, at best, ***only*** the particular cost function disclosed at column 13, using the specific input parameters of partial volume data, CDVHs, zones, and weighting of zones, could have been a contribution to the art. *See* col. 12:34-45.

Moreover, one of skill in the art would have appreciated that the cost function disclosed in column 13 was a non-linear cost function with multiple potential solutions (local minima), and that a stochastic algorithm like simulated annealing, which searches the solution space randomly, was the best algorithm to use with it. Rosen Dec. at ¶¶ 126-28. One of skill in the art would have known that Dr. Carol had prior experience with simulated annealing and in particular, FSA, and had used it in the unpatented, precursor Peacock planning system, and that simulated annealing is especially useful with complex cost functions, and in particular, complex nonlinear cost functions that used CDVH (multiple partial volume data variables). Ex. 22 at 60-65; Ex. 19 at 180; Rosen Dec. at ¶ 105. One of skill in the art also would have appreciated that at the time of filing of the application, this non-linear cost function could not be used with other optimization algorithms without significant experimentation by those of skill in the art. Ex. 22 at 59-61;65-67; Rosen Dec. at ¶ 127.

Skilled artisans would have understood that at each iteration of the simulated annealing algorithm, beam weights would be changed by adding or subtracting beam weight randomly, and that the particular cost function incorporated in the algorithm would compute the total cost of the change to the beam weights according to the formulas disclosed in column 13. The algorithm would then compare the total cost of the change to the beam weights (the proposed solution of the current iteration) to determine whether the solution is better or worse than the total cost of the proposed solution from the previous iteration. Rosen Dec. at ¶¶ 93, 133. The simulated annealing algorithm would accept the proposed solution if the cost was lower than the cost of the previous iteration and reject the proposed solution if the cost was higher. Id. at ¶ 134.

Dr. Carol described a cost function virtually identical in concept to that claimed in the '283 patent in May 1996, months before the filing of the provisional application:

> CORVUS uses a unique Area Cost Function (ACF) which is explicit in its resolution of conflicts. After a CDVH is constructed from user-entered partial volume values, the system divides the CDVH into regions and automatically assigns a relative weight to each. These weights are used to resolve conflicts between the various CDVH regions defined by the target goals and structure limits. The default weights favor structures over targets when such conflicts exist; all structure limits … will be met before target goals are met.

Ex. 3 at 247. Dr. Carol provided further mathematical details of the CORVUS cost function in early 1997:

> CORVUS uses a unique Area Cost Function (ACF) which is explicit in its resolution of conflicts. *After a CDVH is constructed from user-entered partial volume values, the system divides the CDVH into regions and automatically assigns a relative weight to each. Dose is calculated after each* change *to the treatment beams. The total cost of that change is equal to the sum of the cost incurred in each zone (Z) of the CDVH for each target (T) and structure (S)* by the following equations:
>
> CostTotal = ∑Scost + ∑Tcost
> Scost, Tcost = ∑SZcost, ∑TZcost
> ….
> *In layman's terms, if the region under the actual curve is greater than the region under the desired curve, there is a high cost. Thus the system will reject the change that made to the beams and try to find a change which lowers the cost…* By assigning different weights to different zones under the CDVH curve, different results can be obtained. Ex. 5 at 318.

b) "Approach Correspondence of Partial Volume Data…."

One of skill in the art at that time would have understood from the disclosure in the specification and his or her knowledge of CDVH curves, that partial volume data and CDVH curves are consistently used interchangeably in the '283 patent and that partial volume data is used to generate CDVH curves. Skilled artisans understood that "the partial volume data associated with the predetermined desired dose prescription" referred to the partial volume data for each target and structure entered in the Prescription Panel by the user, and that such partial volume data was used to generate a CDVH curve for each target and structure that represented the desired dose prescribed by the physician. Ex. 4 at 247; Ex. 5 at 318; Rosen Dec. at ¶ 130. One of skill in the art also would have appreciated that the comparison between partial volume

data associated with the predetermined desired dose prescription and the partial volume data associated with the proposed radiation beam arrangement was a comparison between the CDVH curves (for the target and each structure) of the desired dose prescription to the CDVH curves of the proposed radiation beam arrangement. *See* Ex. 5 at 317-18; Rosen Dec. at ¶ 132. Further, it was understood that the total cost of the change to the proposed radiation beam arrangement in a given iteration could not be calculated without referring to the CDVH curves because the cost function formulas depend on the CDVH curves, the division of the CDVH curves into zones and the weighting factors for each of those zones for the target and each structure. *Id.* at ¶ 131.

Skilled artisans understood that the partial volume data for each target and structure associated with the proposed radiation beam arrangement was used to generate CDVHs at each iteration for the purpose of comparing it to the CDVHs generated from the partial volume data entered into the Prescription Panel as input and therefore associated with the predetermined desired dose prescription. *Id*. at ¶ 130-32. The cost function compares the CDVH (partial volume data) associated with the predetermined desired dose prescription with the CDVHs (or partial volume data) associated with the proposed radiation beam arrangement at each iteration of the simulated annealing algorithm. Id. By expressing the problem in a clinical way in terms of CDVH curves, Dr. Carol attempted to translate the cost in a way that made sense to clinicians, and could then be translated into mathematics. Id. *See* Ex. 5 at 317-18.

The cost function also measures the total cost of the change to the proposed array of beam weights at a particular iteration of the simulated annealing algorithm based on the formulas disclosed in col. 13. Id. at ¶ 133. The total cost is an abstract concept that does not tell whether the proposed solution is the best solution. Id. Only by comparing the total cost of the proposed beam weight solution of the current iteration to the cost of the proposed beam weight solution of

the previous iteration, could one tell whether the solution is better or worse. *Id.* That comparison is implicit in the terms "greater correspondence" or "lesser correspondence" found in the last "accept or reject" limitation of the asserted claims, as discussed below.

3. BMI's Construction is Divorced from the Intrinsic Record, and Renders Claim 25 Invalid in View of the Prior Art

The cost function cannot be construed to be any broader than the specific disclosure in col. 13. The specification consistently refers to the specific cost function disclosed in Column 13 as "the present invention," and indicates that only the cost function was new. Moreover, various cost functions had previously been incorporated into variants of the simulated annealing algorithm and used to optimize beam weights. Dr. Carol himself had used the Fast Simulated Annealing algorithm with a form of Dr. Webb's cost function in the precursor Peacock system. Thus BMI's construction, which would include ***any*** cost function, cannot possibly be correct. BMI concedes for claim 29 that the claimed cost function is the specific cost function disclosed in Column 13, yet ignores that disclosure in construing the cost function of Claim 25. BMI's construction flies in the face of the intrinsic and extrinsic evidence, and would render the claim invalid for anticipation over a myriad of prior art references, including the inventor's own precursor Peacock system and the Webb references purportedly incorporated by reference in the specification. Assuming, *arguendo*, both constructions are conceivable, it defies belief that the Examiner would have allowed the claims with that interpretation. *See Phillips*, 415 F.3d at 1328 (claims construed to preserve validity where PTO would have recognized that one claim interpretation would render the claim invalid, and would not have issued the patent).

BMI further asserts that this limitation does not implicate CDVH curves, and thus the claims are somehow broader. The substitution of "partial volume data" into the claims instead of "CDVH curves," however, does not inevitably broaden their scope. See *Curtiss-Wright Flow*

Control Corp. v. Velan, Inc., 438 F.3d 1374, 1380-81 (Fed. Cir. 2006) (recognizing that "claim drafters can also use different terms to define the exact same subject matter"). The patentee consistently used "partial volume data" interchangeably with "CDVH curves." CDVHs are necessarily implicated in the claims because skilled artisans could not calculate the cost according to the disclosed formulas without referring to the CDVH's.

E. "The computer further adapted to reject the change of the proposed radiation beam arrangement if the change of the proposed radiation beam arrangement leads to a lesser correspondence to the desired dose prescription and to accept the change of the proposed radiation beam arrangement if the change of the proposed radiation beam arrangement leads to a greater correspondence to the desired dose prescription to obtain an optimized radiation beam arrangement"

"The computer further adapted to reject … and to accept …" means: the same computer uses the same simulated annealing optimization algorithm ("SARP"). *See* above at Section VB.

"**The change of the proposed radiation beam arrangement**" means: the new array of proposed beam weights for the beam elements at each orientation resulting from using the simulated annealing ("SARP") algorithm to add or subtract beam weight randomly during a given iteration."

"*Correspondence*" means: The cost function calculates a total dose cost for the change to the proposed radiation beam arrangement which is a metric for how close the partial volume data (or CDVH) of the proposed radiation beam arrangement of the current iteration is to the partial volume data (or CDVH) of the desired dose prescription. To approach correspondence means minimizing the difference between the proposed radiation beam arrangement and the desired dose prescription, or in other words, to minimize the total dose cost.

"Leads to a lesser (greater) correspondence" means: "Comparing the total dosage cost (the output of the cost function) of the changed proposed radiation beam arrangement from the current iteration to the total dose cost (the output of the cost function) of the proposed radiation

beam arrangement from the previous iteration. If the total dosage cost of the changed proposed radiation beam arrangement of the current iteration is less than the total dosage cost of the proposed radiation beam arrangement from the previous iteration, the change to the proposed radiation beam arrangement is accepted. If the total dosage cost of the change to the proposed radiation beam arrangement from the current iteration is greater than the total dosage cost of the proposed radiation beam arrangement from the previous iteration, then the change to the proposed radiation beam arrangement is rejected.

"To obtain an optimized radiation beam arrangement" means to obtain "the optimal array of beam weights for the beam elements at each orientation based on the treatment objectives as expressed in the cost function incorporated in the SARP algorithm**."** *See* above for discussion of construction of "optimized radiation beam arrangement."

1. The Intrinsic Record Supports Accuray's Construction

The specification discloses that the simulated annealing algorithm compares the cost of an array of beam weights proposed during a given iteration to the total cost of an array of beam weights proposed during the previous iteration to determine whether the proposed solution is better or worse than the previous solution. If it is a better solution (as measured by a lower cost and therefore closer to the desired dose prescription), the solution is accepted. If it is a worse solution (as measured by a higher total cost, and therefore further away from the desired dose prescription), the solution is rejected. Although the claim language does not explicitly recite the comparison between the cost of the current iteration with the cost of a previous iteration, it is implicit in the claim terms "greater correspondence" and "lesser correspondence." Whether the proposed solution of the current iteration has a "***greater*** or ***lesser*** correspondence" to the desired dose prescription can only be measured in reference to the proposed solution of the previous iteration.

The specification discloses that the computer running the SARP algorithm either rejects or accepts the change of the proposed radiation beam arrangement depending on the output of the cost function. See col. 9:29-48:

> The optimal beam arrangement is arrived at by computationally increasing [or decreasing] the proposed beam weight iteratively, *incorporating cost functions to ensure that an iterative change in the beam weight would not result in unacceptable exposure to the volumes of tissue or other structures being subjected to the proposed dose*. At each iteration, the dose distribution resulting from the proposed beam selection is compared to a prescribed dose for the tumor volume and surrounding tissue structures. If the increase or decrease in beam weights would lead to a greater correspondence to the desired prescription, the change is accepted . . . .
>
> * * * * * *
>
> In other words, *if the region under the proposed CDVH curve, or pseudo-curve, is greater than the region under the desired CDVH curve, there is a high cost associated with the change to the proposed beam distribution. Thus, the system will reject the change that was made to the beams and will again* attempt *to change the beam weights to lower the total cost* . . . . (col. 13:40-52)

See col. 13:53-col. 14:10 ("By assigning different weights to different zones of the CDVH curves, different results can be obtained...."); see col. 14:50-col. 15:4.

The specification relies on the Webb articles to provide disclosure to support the claim term "the change of the proposed radiation beam arrangement." The Webb articles disclose that, at each iteration of the simulated annealing algorithm, the beam weights are changed by adding random small grains (amounts) of beam weight to create a new proposed array of beam weights. The change of the proposed beam weights is that new proposed array of beam weights for that iteration. The Webb article also explains "greater correspondence" and "lesser correspondence." *See* Dkt. 131 at Ex. 4, p.1352:

> At each offering the dose distribution, resulting from the current ensemble of beam elemental weights, is compared with the prescription and if the attempt at grain placement were to lead to *a greater correspondence* it is accepted and generally vice versa…. In essence, the aim is to minimize the difference between the two.

2. Extrinsic Evidence Further Supports Accuray's Construction

One of skill in the art at the time of filing would have understood from the specification, the Webb articles and knowledge in the art that the simulated annealing algorithm would reject the new proposed array of beam weights if the total cost was higher than the total cost of the proposed (accepted) solution of the previous iteration, and accept the new proposed array of beam weights if the total cost was lower than the total cost of the proposed beam weight solution of the previous iteration because that is how a stochastic algorithm such as simulated annealing finds the best solution. Ex. 4 at 247; Ex. 5 at 317-18; Rosen Dec. at ¶¶ 133-34.

3. BMI's Construction is Divorced From the Specification

BMI seeks to construe the phrases "leads to a lesser/greater correspondence to the desired dose prescription" as "the proposed radiation beam arrangement would cause a dosage of radiation that is further from/closer to the 'desired dose prescription.'" BMI's construction proves Accuray's point. There is no way to know whether a dosage of radiation is "***further from/closer to***" the desired dose prescription, without comparing it to some other dosage. BMI's construction fails to explain what this comparison is. Dictionaries simply cannot explain the specific details of how a stochastic optimization method such as simulated annealing uses a complex non-linear cost function to determine the best dose distribution for a cancer patient, and apparently BMI cannot explain it either.

Because simulated annealing is the only optimization algorithm disclosed , and the only algorithm that can be used with the specific cost function to obtain an "optimized radiation beam arrangement" without the need for further experimentation, Accuray's construction is correct. *See , e.g., Nystrom,* 424 F.3d at 1143-46 (citing *Phillips*, 415 F.3d at 1316) (holding that construction of the term "board" was limited to "wood cut from a log" due to repeated references in the specification that the claimed flooring is made from wood cut from a log); *Warner-Lambert Co. v. Teva Pharms. USA, Inc.*, 418 F.3d 1326, 1341 (Fed. Cir. 2005) (holding that

construing "discoloration" to mean "oxidative discoloration" did not improperly limit claims because "the only type of discoloration referred to in the patent-in-suit is oxidative discoloration").

VI. PROPOSED CLAIM CONSTRUCTION FOR CLAIM 29

The parties agree that claim 29 is written in "means-plus-function" format and thus invokes 35 U.S.C. § 112 ¶ 6. Under § 112 ¶ 6, a patentee is allowed to claim a limitation using functional language, provided that the specification describes a specific structure which constitutes the "means" for performing the claimed function. *DealerTrack v. Huber,* 2012 U.S. App. LEXIS 1161, at *33-34 (Fed. Cir. Jan. 20, 2012) (citing *Blackboard, Inc. v. Desire2Learn, Inc.*, 574 F.3d 1371, 1382 (Fed. Cir. 2009); *Aristocrat*, 521 F.3d at 1333; *WMS Gaming,* 184 F.3d at 1349. Construing a means-plus-function limitation requires two steps: (1) one must first identify the function of the limitation; and (2) one must then look to the specification and identify the corresponding structure for that function. *Biomedino, LLC v. Waters Techs. Corp.*, 490 F.3d 946, 948 (Fed. Cir. 2007) (citing *Med. Instrumentation & Diagnostics Corp. v. Elekta AB*, 344 F.3d 1205, 1210 (Fed.Cir.2003)).

Each of the "means" elements recited in claim 29 is limited to the specific structure disclosed in the specification for performing the claimed function and structural equivalents that perform the identical function. *Mettler-Toledo, Inc. v. B-Tek Scales, LLC, Inc. v. B-Tek Scales, LLC,* Case Nos. 2011-1173, 2011-1200, 2012 U.S. App. LEXIS 2434, at *8-9 (Fed. Cir. Feb. 8, 2012); *Dealertrack,* Inc. v. Huber, Case Nos. 2009-1566, 2009-1588, 2012 U.S. App. LEXIS 1161, at *33-34 (Fed. Cir. January 20, 2012); *Biomedino, LLC,* 490 F.3d at 948 (holding that the indicated structure must limit the claim so as to prevent pure functional claiming.). Further, where (as in claim 29) "the disclosed structure is a computer, or microprocessor, programmed to carry out an algorithm, the [corresponding] structure is not the general purpose computer, but

rather the special purpose computer programmed to perform the disclosed algorithm.'" *Dealertrack,* 2012 U.S. App. LEXIS 1161, at *33-34 (citing *Aristocrat Techs. Austl. PTY Ltd. v. Int'l Game Tech*., 521 F.3d 1328, 1333 (Fed. Cir. 2008); *WMS Gaming v. International Game Technology*, 184 F.3d 1339, 1349 (Fed. Cir. 1999)). Applying these principles, Accuray's proposed constructions for claim 29 are set forth below.

A. "An apparatus for determining an optimized radiation beam arrangement for applying radiation to a tumor target volume while minimizing radiation of a structure volume in a patient, comprising a computer, including:"

Accuray construes this phrase to have the same meaning as the corresponding phrase in claim 25, for all the reasons set forth in Section V.A. above.

B. "Means for Computationally Obtaining a Proposed Radiation Beam Arrangement"

1. The Claimed Function

The recited function is "computationally obtaining a proposed radiation beam arrangement." Accuray construes this functional language to have the same meaning as the corresponding language in claim 25. See Section V.B. above.

2. The Only Corresponding Structure Described in the Specification is a Specific Computer Configured to Run the SARP Algorithm

The specification discloses one—and only one—structure corresponding to a "means for computationally obtaining a proposed radiation beam arrangement," namely, a computer configured to run the simulated annealing ("SARP") algorithm. Accordingly, this limitation is limited to a computer configured to run the SARP algorithm and equivalents that perform the same function. *Mettler Toledo, Inc. v. B-Tek Scales, LLC,* Case Nos. 2011-1173, 2011-1200, 2012 U.S. App. LEXIS 2434, at *8-9 (Fed. Cir. Feb. 8, 2012) (limiting the structure for the disputed means-plus-function claim elements to the only structure described in the specification

for performing the claimed function).

Importantly, the skilled artisan would understand the structure described in the specification for “computationally obtaining a proposed radiation beam arrangement” is a ***specific*** computer, namely a computer configured to run the simulated annealing algorithm. *Aristocrat Techs. Austl. PTY Ltd. v. Int’l Game Tech*., 521 F.3d 1328, 1333 (Fed. Cir. 2008); *WMS Gaming v. International Game Technology*, 184 F.3d 1339, 1349 (Fed. Cir. 1999). The specification ties the computer to optimization software, which is required to perform the beam weight optimization. *See, e.g*., 9:59-64.

According to the specification, the optimization algorithm used to optimize beam weights is a “computational method.” *See* Col. 3:17-52; col.9:29-40. The only computational method described in the specification for obtaining a proposed radiation beam arrangement is simulated annealing. *See* Col. 8:61- 9:48; col. 5:1-3; col. 8:61-67; col. 9: 45-49. The specification and Dr. Webb’s articles (purportedly incorporated by reference), clearly link the SARP algorithm to the recited function of “computationally obtaining a proposed radiation beam arrangement.” *Mettler-Toledo*, 2012 U.S. App. LEXIS 2434, at *8-9 (holding that a court must look to the specification to determine the structures that correspond to the claimed function). See col. 3:17-52; Col. 4:66-Col. 5:3; Col. 5;43-47; col. 6:20-22; col. 7;58-65; Col. 8;60-67. The SARP algorithm referred to in the specification is the work of Dr. Steve Webb. See Dkt. 131 at Ex. 4, pp. 1349-1370; Dkt. 131 at Ex. 5, pp. 1227-1237; *see* 12:34-45.

There is simply no disclosure of any optimization method other than simulated annealing for obtaining a proposed radiation beam arrangement anywhere in the specification or in Dr. Webb’s articles. See Rosen Dec. at ¶ 122. Indeed, it would have been very difficult, and perhaps impossible, to use an optimization method other that simulated annealing to computationally

obtain a proposed radiation beam arrangement based upon the disclosure in the ’283 patent. *Id*. at ¶ 127. While one skilled in the art might have been able to devise a way to use a different algorithm, this would not be a trivial matter, and would have required experimentation to do so. *Id*.

As the specification discloses only one structure for performing the claimed function of “computationally obtaining a proposed radiation beam arrangement,” this means plus function limitation is properly limited to that sole structure – a computer configured to run the SARP algorithm – and structural equivalents that perform the same function. *Mettler-Toledo,* 2012 U.S. App. LEXIS 2434, at *8-9 (“Although generic A/D converters were known in the art, the patentee chose to use means-plus-function language which limits it to the disclosed embodiments and equivalents.”).

3. BMI’s Construction Violates §112 ¶6

BMI argues that the structure corresponding to a “means for computationally obtaining a proposed radiation beam arrangement” “***includes*** a computer programmed to computationally obtain a proposed radiation beam arrangement, and equivalents thereof.” BMI points to a computer running the SARP algorithm as the corresponding structure, but does not limit its construction to that structure. *Biomedino, LLC v. Waters Techs. Corp*., 490 F.3d 946, 948 (Fed. Cir. 2007) (holding that the indicated structure must limit the claim so as to prevent pure functional claiming.). Moreover, BMI does not mention the Webb articles, which provide the detailed disclosure of SARP. BMI’s construction violates the principle that where “the disclosed structure is a computer, or microprocessor, programmed to carry out an algorithm, the [corresponding] structure is not the general purpose computer, but rather the special purpose computer programmed to perform the disclosed algorithm.'" *Dealertrack* 2012 U.S. App. LEXIS

1161, at *33-34; *WMS Gaming v. International Game Technology*, 184 F.3d 1339, 1349 (Fed. Cir. 1999)). For at least these reasons, BMI's construction cannot stand.

C. "Means for Computationally Changing the Proposed Radiation Beam Arrangement Iteratively"

1. The Claimed Function

The recited function is "computationally changing the proposed radiation beam arrangement iteratively." This phrase has the same meaning as the corresponding language in claim 25, as explained above in Section V.C.

2. The Only Corresponding Structure Described in the Specification is a Specific Computer Configured to Run the SARP Algorithm

The *only* structure described in the specification for "computationally changing the proposed radiation beam arrangement iteratively" is a computer that runs a simulated annealing algorithm. *See* col. 9:29-49. And the only disclosure of how the simulated annealing algorithm works to change the proposed radiation beam arrangement is in the Webb publications. The Webb articles explain how the computer uses the simulated annealing algorithm to change the proposed beam weights at each iteration of the simulated annealing algorithm. *See* Webb 1989 at 1352. Webb further explains how the simulated annealing algorithm adds or subtracts the beam weights at each iteration. *See* Dkt. 131 at Ex. 4, pp. 1355-56. Because the SARP algorithm is the *only* structural embodiment provided for performing the recited function, the "means" for computationally changing the proposed radiation beam arrangement iteratively" is limited to this structure – a computer configured to run the SARP algorithm—and structural equivalents that "computationally change the proposed radiation beam arrangement iteratively." *See Mettler-Toledo,* 2012 U.S. App. LEXIS 2434, at *8-9.

3. BMI's Construction Violates §112 ¶6

BMI points to a computer running the SARP algorithm as the structure disclosed in the specification to "computationally change the proposed radiation beam arrangement iteratively," but improperly refuses to limit its construction to that structure and equivalents that perform the same function. *Mettler Toledo*, 2012 U.S. App. LEXIS 2434, at *8-9. Further, BMI fails to cite to the Webb articles, which provide the detailed disclosure of SARP. BMI's construction violates the principle that where "the disclosed structure is a computer, or microprocessor, programmed to carry out an algorithm, the [corresponding] structure is not the general purpose computer, but rather the special purpose computer programmed to perform the disclosed algorithm."' *Dealertrack*, 2012 U.S. App. LEXIS 1161, at *33-34 (citing *Aristocrat Techs. Austl. PTY Ltd. v. Int'l Game Tech*., 521 F.3d 1328, 1333 (Fed. Cir. 2008); *WMS Gaming v. International Game Technology*, 184 F.3d 1339, 1349 (Fed. Cir. 1999)). For at least these reasons, BMI's construction must be rejected.

D. Wherein the Means for Computationally Changing the Proposed Radiation Beam Arrangement Includes a "Means for Changing the Beam Weights"

1. The Claimed Function

The claimed function is "changing the beam weights." This phrase has the same meaning set forth above with regard to the identical language in claim 25. *See* Section V.C. above.

2. The Only Corresponding Structure Disclosed in the Specification is a Specific Computer Configured to Run the SARP Algorithm

The only structure corresponding to "changing the beam weights" is a specific computer configured to run the simulated annealing algorithm. Although the '283 patent specification itself does not describe how the beam weights are changed, the Webb articles provide some disclosure." As discussed above in Section V.C., the Webb 1991 article explains that beam weights are beam intensities and that "the [simulated annealing] method proceeds by adding

'grains of beam intensity' randomly to beam elements…. Grains are small elements of beam intensity, randomly positive and negative." Dkt. 131 at Ex. 5, pp. 1227-29. Again, because the only structure disclosed for performing the recited function is a computer configured to run the SARP algorithm, this means plus function is limited to that structure and equivalent structures that perform the same function. *Mettler-Toledo,* 2012 U.S. App. LEXIS 2434, at *8-9; *Dealertrack,* 2012 U.S. App. LEXIS 1161, at *33-34; *Nomos v. Brainlab,* 357 F.3d 1364, 1368-69 (Fed. Cir. 2004).

3. BMI's Construction Violates § 112 ¶ 6

BMI's construction of "means for changing the beam weights" improperly attempts to broaden the structure to any computer "programmed to change the beam weights and equivalents thereof," even though the structure that BMI points to in the specification in support of its construction is a specific computer running the SARP algorithm. Further, BMI fails to cite to the Webb articles, which provide the detailed disclosure of SARP. For the same reasons as stated above in Section V.C.3., BMI's construction is incorrect. BMI cites to Figures 6A and 6B, as if adding an additional beam changes the beam weights. Such a construction cannot stand.

E. "Means for Incorporating a Cost Function at Each Iteration to Approach Correspondence of Partial Volume Data Associated With the Proposed Radiation Beam Arrangement to Partial Volume Data Associated With a Predetermined Desired Dose Prescription"

1. The Claimed Function"

The claimed function is "incorporating a cost function at each iteration to approach correspondence of partial volume data associated with the proposed radiation beam arrangement to partial volume data associated with a predetermined desired dose prescription." This phrase has the same meaning as the corresponding functional language in claim 25. See Section V.D.

2. The Only Corresponding Structure Disclosed in the Specification is a Specific Computer Configured to Run the

SARP Algorithm

The specification simply does not disclose any structure other than a computer configured to run the SARP algorithm for "incorporating a cost function at each iteration to approach correspondence of partial volume data associated with the proposed radiation beam arrangement to partial volume data associated with a predetermined desired dose prescription." The repeatedly refers to the cost function described in Column 13 as the "cost function of the present invention." See, e.g., col. 13:4-5; col. 15:42-46. The specification further states that, "The cost function of the present invention may be easily incorporated into existing SARP algorithms by one skilled in the art." Col. 15:42-46. The specification does not explain the details of how the simulated annealing algorithm incorporates a cost function at each iteration but, rather leaves that explanation to the Webb articles, which are purportedly incorporated by reference at Col. 12:27-47. See Dkt. 131 at Ex. 5, pp. 1227-29; Dkt. 131 at Ex. 4, pp. 1355-58. Because the patentees chose to disclose only a single structural embodiment for performing this claimed function, this means plus function claim limitation is limited to the sole structure disclosed – namely, a computer configured to run the SARP algorithm—and structural equivalents that "computationally change the proposed radiation beam arrangement iteratively." *Mettler-Toledo,* 2012 U.S. App. LEXIS 2434, at *8-9; *Dealertrack,* 2012 U.S. App. LEXIS 1161, at *33-34; *Nomos,* 357 F.3d at 1368-69.

3. BMI's Construction Violates §112 ¶6

In construing "means for incorporating a cost function . . .", BMI again commits the same legal errors as it did with regard to the preceding limitations of claim 29. Specifically, BMI points to a specific computer which runs the SARP algorithm and the cost function described in Column 13 as support for its construction, but then refuses to construe the phrase as limited to this structure, which is the sole embodiment described in the specification. Further, BMI fails to

cite to the Webb articles, which provide the detailed disclosure of SARP. Also, BMI again fails to limit the structure to a specific computer running a specific algorithm, as required under the case law. Thus, for the same reasons discussed above in Section VI.A-D., BMI's construction fails.

F. "Means for Rejecting the Change of the Proposed Radiation Beam Arrangement if the Change of the Proposed Radiation Beam Arrangement Leads to a Lesser Correspondence to the Desired Dose Prescription and Accepting The Change of the Proposed Radiation Beam Arrangement if the Change of the Proposed Radiation Beam Arrangement Leads to a Greater Correspondence to the Desired Dose Prescription to Obtain an Optimized Radiation Beam Arrangement."

1. The Claimed Function

The claimed function is "rejecting the change of the proposed radiation beam arrangement if the change of the proposed radiation beam arrangement leads to a lesser correspondence to the desired dose prescription and accepting the change of the proposed radiation beam arrangement if the change of the proposed radiation beam arrangement leads to a greater correspondence to the desired dose prescription to obtain an optimized radiation beam arrangement." This phrase has the same meaning as the corresponding functional language recited in claim 25. *See* Section V.E. above.

2. The Only Corresponding Structure Disclosed in the Specification is a Specific Computer Configured to Run the SARP Algorithm

Again, the only structure disclosed in the specification corresponding to "rejecting the change of the proposed radiation beam arrangement if the change of the proposed radiation beam arrangement leads to a lesser correspondence to the desired dose prescription and accepting the change of the proposed radiation beam arrangement if the change of the proposed radiation beam arrangement leads to a greater correspondence to the desired dose prescription to obtain an optimized radiation beam arrangement" is a computer configured to run the simulated annealing

algorithm. The specification refers to only one structure which compares the cost of a proposed radiation beam arrangement (array of beam weights) proposed during a given iteration (as calculated by the cost function in that iteration) to the total cost of a beam arrangement proposed during the previous iteration (as calculated by the cost function in the previous iteration) to determine whether the proposed array of beam weights of the current iteration is a better or worse solution than the proposed array of beam weights of the previous iteration. If it is a worse solution (as measured by a higher total cost, and therefore farther away from the desired dose prescription). "Greater or lesser correspondence" can only be measured in reference to the proposed solution of the previous iteration.

Namely, the sole structure identified by the patentees for performing this function is a computer configured to run the SARP algorithm. The specification teaches that it is the computer running the SARP algorithm which either rejects or accepts the change of the proposed radiation beam arrangement, depending on the output of the cost function. *See* Col. 9:29-48. Because this is the only structure that the patentees chose to disclose for performing the recited function, this means plus function limitation is limited to a computer configured to run the SARP algorithm and structural equivalents that perform the identical function. *Mettler-Toledo,* 2012 U.S. App. LEXIS 2434, at *8-9; *Dealertrack,* 2012 U.S. App. LEXIS 1161, at *33-34; *Nomos,* 357 F.3d at 1368-69.

3. BMI's Construction Violates §112 ¶6

Here again, BMI commits the same legal errors. Specifically, BMI points to a specific computer running the SARP algorithm in the specification as the corresponding structure, but then construes the limitation much more broadly, such that the structure could be any general purpose computer. Further, BMI fails to cite to the Webb articles, which provide the detailed disclosure of SARP. For the same reasons as discussed above, BMI's construction is incorrect.

VII. CLAIMS 25 AND 29 ARE INVALID AS INDEFINITE

A. Claim 25 is Invalid as an Improper Hybrid Claim

Claim 25 is invalid as indefinite under 35 U.S.C. § 112 ¶2 because it improperly combines two separate statutory classes of invention. *IPXL Holdings, L.L.C. v. Amazon.Com, Inc.,* 430 F.3d 1377, 1384 (Fed. Cir. 2005). The preamble indicates that the patentees sought to claim "an apparatus" including a "computer." However the claim limitations references the use of the apparatus to perform a method step, *e.g.,* to "computationally obtain a proposed radiation beam arrangement," "computationally change the proposed radiation bean arrangement iteratively," "chang[e] the beam weights," "incorporate a cost function at each iteration . . ." and "to reject the change of the proposed radiation beam arrangement . . . and to accept the change of the proposed radiation beam arrangement . . . ." Here, as in *IPXL,* it is unclear whether infringement of claim 25 occurs when one creates an apparatus that allows the user to "determine an optimized radiation beam arrangement," or whether infringement occurs when the user actually uses the apparatus to "determine an optimized radiation beam arrangement" by "computationally obtain[ing] a proposed radiation beam arrangement," "computationally chang[ing] the proposed radiation bean arrangement iteratively," "changing the beam weights," "incorporate[ing] a cost function at each iteration . . ." and "reject[ing] the change of the proposed radiation beam arrangement . . . and . . . accept[ing] the change of the proposed radiation beam arrangement . . . ." In short, because claim 25 recites both an apparatus and a method for using that apparatus, it does not apprise a person of ordinary skill in the art of its scope, and is invalid under §112, ¶2.

B. Claim 29 is Invalid as Indefinite Because the Structure Corresponding to Each "Means" Limitation is Not Disclosed in the Specification

Claim 29 is in valid as indefinite under 35 U.S.C. § 112 ¶2 because the specification fails to disclose a specific structure (*i.e.*, algorithm) corresponding to each of the functional limitations

recited in the claim. The parties agree that claim 29 is a "means plus function" claim governed by 35 U.S.C. § 112 ¶ 6. For each alleged "means plus function" limitation of claim 29, BMI contends that the corresponding structure is "a computer programmed" to perform the recited functional limitation. However, the '283 patent specification, within its four corners, fails to describe any specific structure which performs the recited functions of claim 29. *DealerTrack,* 2012 U.S. App. LEXIS 1161, at *33-34 (citing *Blackboard,* 574 F.3d at 1382; *Aristocrat*, 521 F.3d at 1333; *WMS Gaming,* 184 F.3d at 1349. Instead, the specification purports to "incorporate by reference" several publications by Webb that describe a computer programmed to run simulated annealing algorithms. *See* Col. 12:34-45. The specification itself does not describe any such structure, as required by § 112 ¶2. *Pressure Prods. Med. Supplies, Inc. v. Greatbatch Ltd*, 599 F.3d 1308, 1317 (Fed. Cir. 2010); *Biomedino, 4*90 F.3d at 952-53 (structure supporting a means plus function claim cannot be incorporated by reference but must be ***specifically described in the specification***).

VIII. OBJECTION TO EXTRINSIC EVIDENCE AND LENGTH OF HEARING

Accuray objects to BMI's extrinsic evidence. BMI cites to dictionary definitions from English language dictionaries, some of which issued after the patent issued. Extrinsic evidence must relate to the meaning of claim terms to a person of ordinary skill in the art in 1996.

Accuray believes the Special Master's order setting the schedule for the claim construction hearing will provide sufficient time to address the claim construction issues. If the Court would find it helpful, Accuray is prepared to have Dr. Isaac Rosen, an expert in radiation optimization, on hand to provide a tutorial to the Court. *See* Rosen Declaration hereto.

Dated this 29th day of March, 2012.

/s/ Kirsten R. Rydstrom
Kirsten R. Rydstrom
Pa. I.D. No. 76549
REED SMITH LLP
435 Sixth Avenue
Pittsburgh, PA 15219
412-288-3258/7284
fax: 412-288-3063
krydstrom@reedsmith.com

Madison C. Jellins
HelixIP LLP
400 Seaport Court
Suite 105
Redwood City, CA 94063
650-474-0240
mcjellins@helixip.com

Janice Christensen
HelixIP LLP
New York
Counsel for Defendant,
Accuray Incorporated
650-474-0240

CERTIFICATE OF SERVICE

I hereby certify that on March 29, 2012, I electronically filed the foregoing document with the clerk of court for the U.S. District Court, Western District of Pennsylvania, using the electronic case filing system of the court. The electronic case filing system will send notification of such filing to all counsel of record. Counsel may access such document using the Court's system.

/s Kirsten R. Rydstrom
Attorneys for Defendant Accuray Incorporated

Dated: March 29, 2012